IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	**MAIL STOP AMENDMENT**
Peter Kite et al.	Group Art Unit: 1617
Application No.: 10/659,413	Examiner: Shobha Kantamneni
Filed: September 10, 2003	Confirmation No.: 4621
For: ANTISEPTIC COMPOSITIONS, METHODS AND SYSTEMS	

DECLARATION OF

STEPHEN F. OLMSTEAD & PAUL G. KETTERIDGE

UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Stephen F. Olmstead, MD, and Paul G. Ketteridge hereby declare and state under penalty of perjury the following:

1. I, Stephen F. Olmstead, MD, am a physician and scientist. I received my Bachelor of Science degree with distinction from the University of New Mexico with a biology major and chemistry minor. I was awarded Phi Beta Kappa for academic excellence. I received my Medical Degree from the University of New Mexico and was elected to the Alpha Omega Alpha honorary medical society. I completed a residency in internal medicine at the Massachusetts General Hospital and was a Fellow at Harvard Medical School. I completed a fellowship in cardiovascular diseases at the University of Washington. I was on the faculty of the University of Washington School of Medicine from 1986 through 1999. I am presently Chief Science Officer for ProThera, Inc. where I direct basic and clinical research. I am thoroughly familiar with antiseptic solutions, catheter lock flush solutions, biofilm, pharmacology, and toxicology.

2. I, Paul G. Ketteridge, am a pharmacist and regulatory affairs specialist in the US pharmaceutical and medical device industry. After graduating from the University of Washington School of Pharmacy, I accepted a commission in the US Public Health Service. The last 8 years of service in the USPHS were spent at the National Institute of Health and the US Food and Drug Administration. At both of those agencies, I specialized in the development of new medical products for human use, and the regulatory approval of such. Upon leaving the USPHS, I was employed in several small biotech pharmaceutical companies, performing regulatory affairs duties, that is responsible for overseeing all the activities to be sure they complied with all applicable laws and regulations. For the last 13 years, I have served as a consultant in the pharmaceutical and medical device field, advising over 20 companies, US and foreign in the development and ultimate marketing registration of my clients products. This experience has placed me in a position to understand the regulatory approval process in the United States in regard to pharmaceuticals and medical devices. I have detailed knowledge in toxicology testing requirements and product formulations issues required by the US FDA for both initial clinical testing and final marketing approval.

3. The Fahim patent US 6,500,861 B1, hereinafter Fahim, teaches antimicrobial compositions for the expressed purpose of cleansing the skin. Skin cleansers and other topical preparations meant for application on epidermal surfaces may employ active agents and excipients that would be toxic if ingested. For this reason, no medical practitioner or person skilled in the art of antimicrobials would ever find that a patent on a skin cleanser would teach anything obvious to the invention of an antimicrobial for oral or parenteral administration. An obvious example is that plain chlorine bleach, 3–6% sodium hypochlorite (NaClO), is an excellent antimicrobial. While it is irritating to the skin, contact with dilute solutions can be tolerated. However, ingestion of chlorine bleach is highly toxic causing corrosive tissue damage of the gastrointestinal track. Fahim teaches compositions comprised of potentially toxic chemicals unsuitable for oral ingestion or parenteral administration.

4. Fahim teaches 2,4,4'-trichloro-2'-hydroxydiphenyl ether (Triclosan) as a component. While triclosan is used for its antibacterial properties in many

detergents, dish-washing liquids, soaps, deodorants, cosmetics, lotions, anti-microbial creams, various toothpastes, and as an additive in various plastics and textiles, triclosan has never been approved for oral or parenteral administration. Triclosan's use in the preceding applications in no way makes triclosan's use as an oral ingredient self-evident or obvious to sterilize toxic chemicals and administer them parenterally. The safety of triclosan has been questioned in regard to environmental and human health. The United States Environmental Protection Agency (EPA) has registered it as a pesticide. The molecular structure of this compound is similar to some of the more toxic chemicals such as dioxins and PCBs. The EPA gives triclosan high scores both as a human health risk and as an environmental risk. Triclosan is a chlorophenol, a class of chemicals suspected of causing cancer in humans. Externally, phenols can cause a variety of skin irritations, but since they can temporarily deactivate sensory nerve endings, contact with it may cause little or no pain. Taken internally, even in small amounts, phenols can lead to cold sweats, circulatory collapse, convulsions, coma, and death. Reports suggest that triclosan can combine with chlorine in tap water to form chloroform gas (PMID 15926568), which the EPA classifies as a probable human carcinogen. Triclosan was the subject of a United Kingdom cancer alert. Triclosan reacts with the free chlorine in tap water to produce lesser amounts of other compounds, like 2,4-dichlorophenol (PMID 15926568). Most of these intermediates convert into dioxins upon exposure to UV radiation (from the sun or other sources). Dioxins are extremely toxic and are very potent endocrine disruptors. Triclosan has been shown to disrupt testosterone biosynthesis in testicular Leydig cells (PMID 18655822). See Avivia Glaser et al., *Common Antibacterial Soaps Threaten Children's Health and Offer No Added Protection From Bacteria*, Beyond Pesticides.

5. Fahim teaches 4-chloro-3,5-dimethyl phenol (Chloroxylenol, also known as parachlorometaxylenol or PCMX) as a component. While chloroxylenol is used as an antimicrobial in soaps, shampoos, and sprays, it has never been approved for oral or parenteral administration. Despite its topical use, chloroxylenol may be a skin, eye or respiratory tract irritant and is considered harmful if swallowed. See http://msds.chem.ox.ac.uk/CH/4-chloro-3,5-dimethylphenol.html. This again

undersores that there is nothing in Fahim that makes it relevant to any bactericidal application except topical uses. The PAN Pesticides Database maintained by the Pesticide Action Network North America (http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35209) notes that chloroxylenol is highly corrosive and causes caustic eye, skin, mouth and gastrointestinal injuries. Ingestion can result in nausea, vomiting, diarrhea, hypotension, myocardial failure, pulmonary edema, neurological changes, liver and renal toxicity, methemoglobinemia, and hemolysis. It is readily apparent that this component of Fahim cannot be sterilized, placed in a vial, and administered to humans. No reasonable practitioner skilled or even unskilled in the art would even think about doing this.

6. Chloroxylenol is shown to have an LD_{50} (oral injection) for a mouse of 1,000 mg/kg and an LD_{50} (oral injection) for a rat of 3830 mg/kg. See Material Safety Data Sheet, *4-Chloro-3,5-dimethylphenol, 99%*, 2001, available at http://newsearchch.chemexper.com/cheminfo/servlet/org.dbcreator.MainServlet?action=PowerSearch&query=msds._msdsID%3D7886&sort=&target=msds&from=0&realQuery=rn.value%3D%3D%2288-04-0%22&searchTemplate=rn.value%3D%3D%3F&searchValue=88-04-0&history=off&options=brandqtyoffer&format=ccd (last visited January 14, 2010).

7. Fahim teaches glutaraldehyde as a component. Glutaraldehyde is a toxic substance that has not been approved by the FDA for inclusion in antibacterial hand soap. See Dan Wagner, *ISSA's Guide to the Regulation of Antibacterial Hand Soaps*, 2003 - and - *GLUTARALDEHYDE*.

8. According to the National Institute for Occupational Safety and Health, workers exposed to glutaraldehyde through inhalation or skin contact, may experience the following health effects: throat or lung irritation; asthma and difficulty breathing; contact and/or allergic dermatitis; nasal irritation; sneezing; wheezing; burning eyes and conjunctivitis. See National Institute for Occupational Safety and Health, *Glutaraldehyde*, 2009, available at http://www.cdc.gov/niosh/topics/glutaraldehyde/ (last visited January 14, 2010).

9. Also, according to the National Institute for Occupational Safety and Health, glutaraldehyde is shown to have a very low intravenous LD_{50} in a rat of just 9.8 mg/Kg. When administered orally to rats the LD_{50} is 134 mg/Kg. (See National Institute for Occupational Safety and Health, *Glutaraldehyde RTECS*, 2009, available at http://www.cdc.gov/niosh/rtecs/ma256250.html and http://www.scholarchemistry.com/msds/Glutaraldehyde.pdf.) LD_{50} is an abbreviation for "Lethal Dose 50%" and is the median lethal dose of a toxic substance which will kill half the members of a tested population. LD_{50} figures are used as a general indicator of a substance's acute toxicity. The LD_{50} is usually expressed as the mass of substance administered per unit body weight of the test subjects, such as grams of substance per kilogram of body weight. Expressing the lethal dose in this manner allows the relative toxicity of different substances to be compared and normalizes the toxic amounts for the different sizes of laboratory test animals. Typically, the LD_{50} of a substance is given in milligrams per kilogram of body weight.

10. A substance is considered highly toxic when the LD_{50} is more than 50 milligrams per kilogram but not more than 500 mg/Kg of body weight when administered orally to albino rats. See http://www.scripps.edu/researchservices/ehs/chemicalsafety/LD50.html. Glutaraldehyde is therefore a highly toxic substance. When ingested or given pareterally, glutaraldehyde is a poison.

11. Fahim (WO 00/13656) shows in the Examples a concentration of glutaraldehyde ranging from 0.1 wt% to 0.125 wt %. See *Fahim*, Examples 1-9 (Ucarcide 250 (50% wt% glutaraldehyde)). To reach the LD_{50} (intravenous) level of 9.8 mg/kg in an average rat (400 g), would require an intravenous injection of about 4 mL of a water solution with 0.1 wt% glutaraldehyde.

12. Fahim teaches ethylene diamine tetra acetic acid (EDTA) preferably as the tetrasodium salt as a component. It must be noted that Fahim does not teach that tetrasodium EDTA is an antimicrobial. It is specifically added to enhance the antimicrobial properties of the "combination of antimicrobial ingredients, i.e., PCMX,

triclosan, and glutaraldehyde". Fahim, page 9, lines 11,12. EDTA is specifically not mentioned as an antimicrobial. The practical use of the EDTA is to allow a reduced amount of PCMX which has an unpleasant odor. Fahim, page 10.

13. Triclosan and chloroxylenol are poorly or insoluble in water. No one skilled in the art would ever conceive of sterilizing a poorly soluble antimicrobial soap for parenteral administration. It would not mix with blood and other body fluids.

14. The Fahim antimicrobial cleansing solution cannot be sterilized by the methods of Wider which is heat. Triclosan is heat stable only up to 482°F (250°C), but it readily decomposes into dioxins. Dioxins are a poison that accumulates in the body and contributes to cancer, liver damage and an elevated risk of diabetes. Glutaldehyde is volatile and cannot withstand temperatures required for sterilization. Each of the embodiments of Fahim's teachings contains propylene glycol. Any solution containing propylene glycol in a container will explode on heating. The flash point is 99°C (210°F). See MSDS for propylene glycol.

15. Wider arrives at pyrogen free compositions by using USP grade products. USP refers to the United States Pharmacopeia, an official public standards–setting authority for all prescription and over–the–counter medicines and other health care products manufactured or sold in the United States. Wilder also calls for use of food grade components which will have no pyrogen specification and are not sterile. Pyrogens are not an issue in products used as food. However, they are only a major concern in formulations that come in contact with the systemic circulation (i.e. blood stream)ven if sterile, pyrogen-free, deionized water (as used in Wider) were used with the Fahim composition, the final product would be very difficult to render pyrogen free since none of the other ingredients are ready available with a specification of low or no pyrogens. Pyrogens are very difficult and expensive to remove from a final formulation, and the acceptable production method to assure no pyrogens in a final formulation is to only utilize ingredients containing no pyrogens. Typically, ingredients intended for injection into the body are available in a pyrogen free presentation. However, since the discussed ingredients contained in the Fahim

formulations are never used in products intended to be injected or otherwise contact the systemic circulation, they are not available with a specification of pyrogen free.

16. The Fahim cleansing solution cannot be sterilized by filtration. The viscosity of the Fahim hand soap compositions is 780 and 900 centipoise (cps) respectively. As a reference, the viscosity of water is 1 cps while the viscosity of SAE 40 motor oil is 650 to 900 cps. The Fahim soaps are as viscous and thick as motor oil. This would preclude filtration for sterilization. It is not only not obvious to sterilize the Fahim compositions, it is not possible to do so. Accordingly, no one skilled in the art would think to do so.

17. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 10001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____ By: _____
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Date: _____ By: _____
Paul G. Ketteridge

Patent
Attorney's Docket No. 1024637-000191

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15. Wider arrives at pyrogen free compositions by using USP grade products. USP refers to the United States Pharmacopeia, an official public standards–setting authority for all prescription and over–the–counter medicines and other health care products manufactured or sold in the United States. Wilder also calls for use of food grade components which will have no pyrogen specification and are not sterile. Pyrogens are not an issue in products used as food. However, they are only a major concern in formulations that come in contact with the systemic circulation (i.e. blood stream)ven if sterile, pyrogen-free, deionized water (as used in Wider) were used with the Fahim composition, the final product would be very difficult to render pyrogen free since none of the other ingredients are ready available with a specification of low or no pyrogens. Pyrogens are very difficult and expensive to remove from a final formulation, and the acceptable production method to assure no pyrogens in a final formulation is to only utilize ingredients containing no pyrogens. Typically, ingredients intended for injection into the body are available in a pyrogen free presentation. However, since the discussed ingredients contained in the Fahim

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17. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 10001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the application or any patent issued thereon.

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ATTACHMENTS

Common Antibacterial Soaps Threaten Children's Health and Offer No Added Protection From Bacteria

by Aviva Glaser, Beyond Pesticides

In a world full of germs and viruses, antibacterial products may seem like an easy way to stay healthy, but a close look at them reveals that they present a serious threat to public health and the environment. Over the last two decades, antibacterial products have swarmed the marketplace, showing up in hundreds of different products, in everything from soaps and toothpastes to clothes, kitchenware, and toys. In fact, a study done in 2000 found that over 75% of liquid soaps and nearly 30% of bar soaps—45% of all the soaps on the market—contain some type of antibacterial agent. The most common active ingredient was triclosan, a chemical that is used so commonly it actually makes its way into our bodies. A 2002 Swedish study found high levels of triclosan in 3 out of 5 human breast milk samples.

Under the appropriate settings and conditions—such as in hospitals, to prevent hospital-acquired infections—triclosan has been proven effective. But no current data demonstrate any extra health benefits from the use of antibacterial soap and cleanser in a healthy household. A study of over 200 healthy households found that households using antibacterial products did not have any reduced risk for runny noses, coughs, and other symptoms of infectious diseases. According to the American Medical Association, "Despite their recent proliferation in consumer products, the use of antimicrobial agents such as triclosan in consumer products has not been studied extensively. No data exist to support their efficacy when used in such products or any need for them ... It may be prudent to avoid the use of antimicrobial agents in consumer products ...."

Cancer and Triclosan

There have been reports of acute health effects such as skin irritation resulting from triclosan exposure. But the more worrisome health effects of triclosan are more subtle. Researchers have raised concerns about triclosan and its link to dioxins, which are highly carcinogenic chemicals that can cause severe health problems such as:

- weakening of the immune system,
- decreased fertility,
- altered sex hormones,
- birth defects, and
- cancer.

Even relatively small quantities of dioxins can have devastating effects. According to EPA, triclosan "could be" and is "suspected to be" contaminated with dioxins. Dioxins can be found in triclosan as impurities formed during the manufacturing process. Researchers who added triclosan to river water and exposed it to ultraviolet light found that a significant portion of the triclosan was converted to dioxins, raising fears that sunlight could transform triclosan to dioxins naturally.

Girl Scouts Say No To Triclosan

A group of curious Girl Scouts in St. Paul, Minnesota found that when they tried to use triclosan to kill bacteria they were growing for a science fair project, the bacteria actually started growing. After a two-year investigation, the girls found that while anti-bacterial soap kills 99.6% of germs, regular soap kills 99.4% of germs. The Girl Scouts concluded that household anti-bacterial products are unnecessary, and that by not quite killing all the bacteria, they could actually create super-germs that will pose a threat to public health. Based on their findings, these young girls have met with local lawmakers who have submitted a bill on the girls' behalf that would ban the use of triclosan.

Another serious health threat stems from interactions between triclosan and tap water. A new study by researchers at Virginia Polytechnic Institute finds that triclosan reacts with chlorine molecules in tap water to form chlorinated dioxins, which are highly toxic forms of dioxin. Because the study was conducted using triclosan-containing dishwashing soap, researchers believe that these chlorinated dioxins are forming in kitchen sinks across the country. The same study also found that the combination of tap water and triclosan produces significant quantities of chloroform, which is a probable human carcinogen. Production of chloroform and dioxins may also be a problem in pools, where there are high levels of chlorine that can react to triclosan residues on people's skin.

Triclosan and Allergies

Overuse of triclosan (and other antibacterials) is also linked to allergies. This is based on the "hygiene hypothesis," which theorizes that there is a correlation between "too much hygiene" and increased allergies and asthma. The concept is that children who are raised in an overly clean environment have immune systems that are not challenged and thus do not develop and mature properly. This hypothesis is based on studies that have found an increase in the frequency of allergies, asthma, and eczema in persons who have been raised in more sterile and hygienic environments.

Triclosan and Antibiotic Resistance

Many recent studies have raised serious concerns that triclosan may promote the emergence of bacteria that are resistant to antibiotics. One concern is that bacteria will become resistant to antibacterial products like triclosan, rendering those antimicrobial products useless to those who truly need them, such as people with compromised immune systems.

Scientists also worry that because triclosan kills bacteria in a similar way as antibiotics, bacteria that

Products Containing Triclosan

The following products all contain triclosan. Caveat emptor!

Soaps:

- Clean & Clear Foaming Facial Cleanser
- Clearasil® Daily Face Wash
- CVS Antibacterial Soap
- DermaKleen™ Antibacterial Lotion Soap
- Dermatologica® Skin Purifying Wipes
- Dial® Liquid Soap
- Jergens Antibacterial® Antibacterial Cream Soap
- Naturade Aloe Vera 80® Antibacterial Soap
- Provon® Soap
- pHisoderm Antibacterial Skin Cleanser
- Softsoap® Antibacterial Liquid Hand Soap
- Tea Tree Therapy™ Liquid Soap

Dental Care:

- Colgate Total®; Breeze™ Triclosan Mouthwash
- Reach® Antibacterial Toothbrush
- Janina Diamond Whitening Toothpaste

Cosmetics:

- Supre® Café Bronzer™
- TotalSkinCare Makeup Kit
- Garden Botanika® Powder Foundation
- Mavala Lip Base
- Jason Natural Cosmetics
- Blemish Cover Stick
- Movate® Skin Litening Cream HQ
- Paul Mitchell Detangler Comb
- Revlon ColorStay LipSHINE Lipcolor Plus Gloss
- Dazzle

Deodorant:

- Arm & Hammer Essentials Natural Deodorant
- Old Spice High Endurance Stick Deodorant
- Right Guard Sport Deodorant
- Queen Helene® Tea Trea Oil Deodorant and Aloe Deodorant
- Nature De France Le Stick Natural Stick Deodorant

become resistant to triclosan will also be resistant to antibiotics. Triclosan does not actually cause a genetic mutation in the bacteria—which is part of the process by which they acquire resistance—but by killing the normal bacteria, it creates an environment where mutated bacteria that are resistant to triclosan are more likely to survive and reproduce. Laboratory studies with triclosan have already found a number of different strains of mutated bacteria that are resistant to triclosan and to certain antibiotics.

Antibiotic resistance has become an increasingly serious problem worldwide, and overuse of triclosan may exacerbate this problem.

Environmental Effects—Triclosan in Wastewater

Over 95% of triclosan uses are in consumer products that are eventually disposed of down sink drains. Wastewater treatment plants cannot remove triclosan from water, so large quantities of triclosan are continuously discharged into local waterways. Numerous studies have detected triclosan in streams and rivers. In a US Geological Survey study of 95 organic wastewater contaminants in US streams, triclosan was one of the most frequently detected compounds, and at some of the highest concentrations observed.

Triclosan is highly toxic to algae. Because algae are the first-step producers in aquatic ecosystems, researchers believe that high levels of triclosan discharged into the environment may destroy the balance of aquatic ecosystems. The risks are especially high

- DeCleor Deodorant Stick
- Epoch® Deodorant with Citrisomes
- X Air Maximum Strength Deodorant

Other Personal Care Products:

- Gillette® Complete Skin Care MultiGel Aerosol Shave Gel
- Murad Acne Complex® Kit®
- Diabet-x™ Cream
- T.Taio™ sponges and wipes
- Aveeno Therapeutic Shave Gel

First Aid:

- SyDERMA® Skin Protectant plus First Aid Antiseptic
- Solarcaine®
- First Aid Medicated Spray; Nexcare™ First Aid
- Skin Crack Care
- First Aid/Burn Cream
- HealWell® Night Splint
- 11-1X1: Universal Cervical Collar with Microban

Kitchenware:

- Farberware® Microban Steakknife Set and Cutting Boards
- Franklin Machine Products FMP Ice Cream Scoop SZ 20 Microban
- Hobart Semi-Automatic Slicer
- Chix® Food Service Wipes with Microban
- Compact Web Foot® Wet Mop Heads

Computer Equipment:

- Fellowes Cordless Microban Keyboard and Microban Mouse Pad

Clothes:

- Teva® Sandals
- Merrell Shoes
- Sabatier Chef's Apron
- Dickies Socks
- Fruit of the Loom Socks
- Biofresh® Socks

Childrens Toys:

- Playskool® :
  - Stack 'n Scoop Whale
  - Rockin' Radio
  - Hourglass
  - Sounds Around Driver
  - Roll 'n' Rattle Ball
  - Animal Sounds Phone
  - Busy Beads Pal
  - Pop 'n' Spin Top
  - Lights 'n' Surprise Laptop

Other:

immediately downstream from wastewater treatment plants.

- Bionare® Cool Mist Humidifier
- Microban® All Weather Reinforced Hose
- Thomasville® Furniture
- Deciguard AB Ear Plugs
- Bauer® 5000 Helmet
- Aquatic Whirlpools
- Miller Paint Interior Paint
- QVC® Collapsible 40-Can Cooler
- Holmes Foot Buddy™ Foot Warmer
- Blue Mountain Wall Coverings
- California Paints®
- EHC AMRail Escalator Handrails
- Dupont™ Air Filters
- Durelle™ Carpet Cushions
- Advanta One Laminate Floors
- San Luis Blankets
- J Cloth® towels
- JERMEX mops

— *Beyond Pesticides*

Staying Clean and Healthy Without Triclosan

When used outside of health care settings, triclosan is unnecessary, and constant exposure to triclosan becomes a health and environmental hazard. The best solution to preventing infections is good old soap and water.

Here are some guidelines on how to stay protected from bacteria without antimicrobials:

- Wash hands frequently and thoroughly. Regular soap lowers the surface tension of water, helping it attach to and wash away unwanted bacteria. Lather your hands for at least 10 to 15 seconds and then rinse them off in warm water. It is important to wash your hands often, especially when handling food, before eating, after going to the bathroom, and when someone in your house is sick.
- Take time to teach children the correct way to wash their hands.
- Dry hands with a clean towel to help brush off any germs that did not get washed down the drain.
- Wash surfaces that come in contact with food with a detergent and water.
- Wash children's hands and toys regularly to prevent infection.

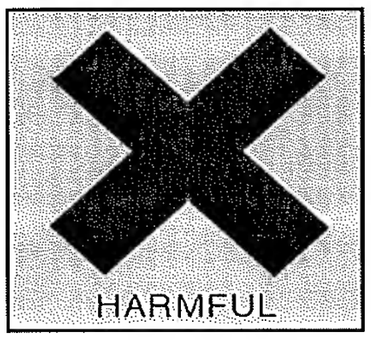
Because triclosan has become so common in soaps and toiletries, be sure to carefully read all ingredients when buying these products. ***Triclosan is also known as Irgasan and Microban.***

Check with your school to see if it uses triclosan-containing products in its classrooms and bathrooms. If you feel like you need antibacterial

protection, there are some essential oils that have antimicrobial properties, such as Australian tea tree oil and grapefruit seed extract, which are sometimes included in natural soaps. Alcohol-based antibacterial soaps, such as Purell, do not carry the same risks of antibiotic resistance and dioxin contamination as triclosan-containing products.

Beyond Pesticides (formerly known as the National Coalition Against the Misuse of Pesticides) works with allies in protecting public health and the environment to lead the transition to a world free of toxic pesticides. Be sure to check out their very informative pesticide fact sheets. You can see the triclosan fact sheet here (opens as PDF). You can call Beyond Pesticides in Washington D.C. at 202-543-5450.

Safety data for 4-chloro-3,5-dimethylphenol



Glossary of terms on this data sheet.

The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers.

General

Synonyms: 4-chloro-3,5-xylenol, p-chloro-m-xylenol, 2-chloro-5-hydroxy-m-xylene, 3,5-dimethyl-4-chlorophenol, 2-chloro-m-xylenol, 2-chloro-5-hydroxy-1,3-dimethylbenzene, benzytol, dettol, husept extra, chloroxylenol (British Pharmacopoeia), nipacide PX, PCMX, ottasept, para-chloro-meta-xylenol
Use: broad spectrum bactericide, used in soaps, shampoos, bactericidal sprays
Molecular formula: $ClC_6H_2(CH_3)_2OH$
CAS No: 88-04-0
EINECS No:

Physical data

Appearance: white or cream crystalline powder with a characteristic odour
Melting point: 114 - 116 C
Boiling point:
Vapour density:
Vapour pressure:
Density (g cm^{-3}):
Flash point:
Explosion limits:
Autoignition temperature:
Water solubility: very slight

Stability

Stable. Incompatible with strong oxidizing agents.

Toxicology

Harmful if swallowed. May act as a mild skin, eye or respiratory irritant.

Toxicity data
(The meaning of any toxicological abbreviations which appear in this section is given here.)
ORL-RAT LD50 3830 mg kg^{-1}
SKN-RBT LD50 > 1000 mg kg^{-1}

Risk phrases
(The meaning of any risk phrases which appear in this section is given here.)
R22 R36 R37 R38.

Transport information

(The meaning of any UN hazard codes which appear in this section is given here.)

Personal protection

Safety glasses, adequate ventilation.

Safety phrases
(The meaning of any safety phrases which appear in this section is given here.)

[Return to Physical & Theoretical Chemistry Lab. Safety home page.]

PAN Pesticides Database - Chemicals

Chloroxylenol - Identification, toxicity, use, water pollution potential, ecological toxicity and regulatory information

Note: See Working with the Information on this Page section below for important notes about this data.

This database and website are updated and enhanced by Pesticide Action Network North America (PANNA). The project is made possible by our Sponsors and by PANNA general funds. We need your support to maintain and improve this system. Please support the database and website — donate to PANNA.

Chemical ID	Identifying information, including synonyms, ID numbers, use type, chemical classification, a link to a list of all products containing this chemical and a list of the top crops this pesticide is used on in California.
Poisoning Symptoms	Signs and symptoms of poisoning, first aid, and links to treatment information for this chemical.
Toxicity	Toxicity to humans, including carcinogenicity, reproductive and developmental toxicity, neurotoxicity, and acute toxicity.
Regulatory	Links to world-wide registration status as well as regulatory information for the U.S. and California.
Water	Water quality standards and physical properties affecting water contamination potential.
Ecotoxicity	Toxicity to aquatic organisms.
Related Chems	List of chemicals in the same family, including breakdown products, salts, esters, isomers, and other derivatives.

Chemical Identification and Use for Chloroxylenol

Top

Basic Identification Information About This Chemical

Chemical Name:	Chloroxylenol
CAS Number:	88-04-0
U.S. EPA PC Code:	086801
CA DPR Chem Code:	925
Molecular Weight:	0
Use Type:	Microbiocide
Chem Class:	Chlorinated phenol

View Related Chemicals

Additional Resources About This Chemical Class and Use Type

See the Global Pesticide Resources page for many additional links.

Other Names for this Chemical

About Chemical Synonyms

00925 (CA DPR Chem Code) , 086801 (US EPA PC Code) , 2-Chloro-5-hydroxy-m-xylene , 3,5-Dimethyl-4-chlorophenol , 3,5-Xylenol, 4-chloro- , 4-Chloro-3,5-dimethylphenol , 4-Chloro-3,5-xylenol , 88-04-0 (CAS Number) , 88040 , 88040 (CAS Number) , 925 (CA DPR Chem Code) , Benzytol , Chloro-xylenol , Chloroxylenol , Desson , Dettol , Dettol, liquid antiseptic , Espadol , Husept Extra , Ottasept , Ottasept Extra , p-Chloro-m-xylenol , Parachlorometaxylenol , PCMX , Phenol, 4-chloro-3,5-dimethyl- , RBA 777 , Septiderm-Hydrochloride

Products Containing This Chemical

Current and historic U.S. registered products

View U.S. Products (•) All Products ( ) Currently Registered Products

Signs and Symptoms of Chloroxylenol Poisoning

Top

NOTE! There may be other diseases and chemicals that have similar symptoms.

If you have a poisoning emergency in the United States call 1-800-222-1222.
If the victim has collapsed or is unconscious, call 911.

Chloroxylenol is a Phenol or Cresol compound.

Report a Poisoning

Find Products Containing this Chemical

Symptoms of Poisoning with Phenol or Cresol Compounds

- Highly corrosive.
- Caustic eye, skin, mouth and gastrointestinal injuries.
- Nausea, vomiting, and diarrhea.
- Hypotension, myocardial failure, pulmonary edema, neurological changes, liver and renal toxicity, methemoglobinemia and hemolysis.

Source for Group Symptoms: Recognition and Management of Pesticide Poisoning, 5th edition, U.S. EPA, Chapter 19.

Treatment for Phenol or Cresol Poisoning

See: Recognition and Management of Pesticide Poisoning, 5th edition, U.S. EPA, Chapter 19, page 203.

Toxicity Information for Chloroxylenol

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Note: Information for many chemicals is incomplete and may not be fully representative of effects on humans. Why?

Summary Toxicity Information

PAN Bad Actor Chemical [1]	Acute Toxicity [2]	Carcinogen	Cholinesterase Inhibitor	Ground Water Contaminant	Developmental or Reproductive Toxin	Endocrine Disruptor
☠	☠	?	No	?	?	?

☠ Indicates high toxicity in the given toxicological category.

? Indicates no available weight-of-the-evidence summary assessment. For additional information on toxicity from scientific journals or registration documents, see the "Additional Resources for Toxicity " section of the chemical detail page.

1. **PAN Bad Actors** are chemicals that are one or more of the following: highly acutely toxic, cholinesterase inhibitor, known/probable carcinogen, known groundwater pollutant or known reproductive or developmental toxicant. NOTE! Because there are no authoritative lists of Endocrine Disrupting (ED) chemicals, EDs are not yet considered PAN Bad Actor chemicals.

2. The acute toxicity reported on this page is of the pure chemical ingredient only and may not reflect the acute toxicity of individual pesticide products. To view acute toxicity of individual products, click on 'View Products' link in the 'Chemical Identification' section above.

Additional Resources about the Toxicity of this Chemical

Additional Toxicity Info for this Chemical

See the Global Pesticide Resources page for many additional links.

Detailed Toxicity Information

Acute Toxicity [2]	Chloroxylenol
WHO Acute Hazard	Not Listed
TRI Acute Hazard	Not Listed
Material Safety Data Sheets	Not Available
Acute rating from U.S. EPA product label	Highly Toxic
U.S. NTP Acute Toxicity Studies	No NTP Studies
View Studies	
Cholinesterase Inhibitor	No

2. The acute toxicity reported on this page is of the pure chemical ingredient only and may not reflect the acute toxicity of individual pesticide products. To view acute toxicity of individual products, click on 'View Products' link in the 'Chemical Identification' section above.

Cancer Information	Chloroxylenol
IARC Carcinogens	Not Listed
U.S. NTP Carcinogens	Not Listed
California Prop 65 Known Carcinogens	Not Listed
U.S. EPA Carcinogens	Not Listed
TRI Carcinogen	Not Listed

Endocrine Disruption	Chloroxylenol
Illinois EPA list	Not Listed
Keith list	Not Listed
Colborn list	Not Listed
Benbrook list	Not Listed
Danish Inert list	Not Listed
EU list	Not Listed

Reproductive and Developmental Toxicity	Chloroxylenol
CA Prop 65 Developmental Toxin	Not Listed
U.S. TRI Developmental Toxin	Not Listed
CA Prop 65 Female Reproductive Toxin	Not Listed
CA Prop 65 Male Reproductive Toxin	Not Listed
U.S. TRI Reproductive Toxin	Not Listed

Chemicals of Special Concern	Chloroxylenol
PAN Bad Actors	Yes
PAN Dirty Dozen list	Not Listed

Water Pollution Potential and Criteria for Chloroxylenol

Top

Water Pollution Potential

PAN Ground Water Contaminant Rating Insufficient Data

Sorry, no water quality standards or criteria have been established for this chemical by the U.S. or Canadian governments; however, there may be criteria established for related chemicals.

Regulatory Information for Chloroxylenol

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International Regulatory Status

Registration in Selected Countries	Registration in Selected Countries: Chloroxylenol
UNEP Persistent Organic Pollutant (POP)	Not Listed
UNEP Prior Informed Consent Chemical (PIC)	Not Listed
WHO Obsolete Pesticide	Not Listed

U.S. and California Regulatory Status

U.S. EPA Registered	Yes
U.S. EPA Hazardous Air Pollutant	Not Listed
U.S. EPA Minimum Risk Pesticide (25b list)	No
CA Registered	Yes
CA Groundwater Contaminant	Not Listed
CA Toxic Air Contaminant	Not Listed

Maximum Tolerance and Residue Levels

Codex Alimentarius (UN FAO Maximum Residue Limits)	Go to web site
U.S. Maximum Tolerance Levels	Go to web site
European Union Maximum Residue Levels	Go to web site

Ecotoxicity for Chloroxylenol

Top

Note! Information for many chemicals is incomplete and may not be fully representative of effects on the environment. Why? Click on underlined terms for definitions and additional information.

Aquatic Ecotoxicity

All Toxic Effects for Organism Group	
Organism Group	Effects Noted

Crustaceans	Behavior
Fish	Mortality
Molluscs	Mortality
Zooplankton	Intoxication
~ Un-Assigned	Mortality
View All Aquatic Ecotoxicity Studies and References	

Summary of Acute Toxicity for Organism Group

Organism Group	Average Acute Toxicity	Acute Toxicity Range
Fish	Moderately Toxic	Moderate to High Toxicity
~ Un-Assigned	Highly Toxic	Highly Toxic
View All Acute Summaries		

Terrestrial Ecotoxicity

We are seeking funding to incorporate terrestrial ecotoxicity data analogous to the aquatic ecotoxicity data in the space above. Watch this space!

Top

Related Chemicals for Chloroxylenol

CAS Number	Relation	Reason	Chemical Name	Chem Detail	Registration	Symptoms	California Use	Chem Use Type	U.S. EPA Reg	PAN Bad Actor
88-04-0	Parent	P	Chloroxylenol	View	View	View	View	Microbiocide	Yes	Yes

Working with the Information on this Page

Click on underlined terms for definitions or go to the Pesticide Tutorial overview page.

Any underlined term with a book icon has additional information.

* Data marked with an asterisk indicates that this chemical is not explicitly listed on the corresponding list. Instead, it belongs to a group of chemicals that IS designated on the list. For example, if an agency assigns a classification of reproductive toxicant to "mercury compounds", that classification is applied to all mercury compounds in the PAN Pesticide database, which are then marked with an asterisk.

To print this page, choose **Print**. To export this data, choose **Save As** 'HTML Source' and open it in Excel or equivalent program.

EN

**** MATERIAL SAFETY DATA SHEET ****

4-Chloro-3,5-dimethylphenol, 99%

**** SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION ****

MSDS Name: 4-Chloro-3,5-dimethylphenol, 99%
Catalog Numbers:
10906-0000, 10906-0050, 10906-1000, 10906-5000
Synonyms:
4-Chloro-3,5-xylenol; PCMX
Company Identification (Europe): Acros Organics BVBA
Janssen Pharmaceuticalaan 3a
2440 Geel, Belgium
Company Identification (USA): Acros Organics
One Reagent Lane
Fairlawn, NJ 07410
For information in North America, call: 800-ACROS-01
For information in Europe, call: 0032(0) 14575211
For emergencies in the US, call CHEMTREC: 800-424-9300
For emergencies in Europe, call: 0032(0) 14575299

**** SECTION 2 - COMPOSITION, INFORMATION ON INGREDIENTS ****

CAS#	Chemical Name	%	EINECS#	Haz Symbols	Risk Phrases
88-04-0	4-Chloro-3,5-dimethylphenol	99%	201-793-8		

Hazard Symbols: XN
Risk Phrases: 22 36/38 43

**** SECTION 3 - HAZARDS IDENTIFICATION ****

EMERGENCY OVERVIEW

Harmful if swallowed. Irritating to eyes and skin. May cause sensitization by skin contact.

Potential Health Effects

Eye:
Causes eye irritation.

Skin:
Causes skin irritation. May be harmful if absorbed through the skin. May cause sensitization by skin contact.

Ingestion:
Harmful if swallowed. May cause irritation of the digestive tract.

Inhalation:
May cause respiratory tract irritation. May be harmful if inhaled.

Chronic:
Not available.

**** SECTION 4 - FIRST AID MEASURES ****

Eyes:
Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.

Skin:
Get medical aid. Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

Ingestion:
Get medical aid. Wash mouth out with water.

Inhalation:
Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.

Notes to Physician:
Treat symptomatically and supportively.

**** SECTION 5 - FIRE FIGHTING MEASURES ****

General Information:
As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

Extinguishing Media:
Use water spray, dry chemical, carbon dioxide, or chemical foam.

**** SECTION 6 - ACCIDENTAL RELEASE MEASURES ****

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks:

Vacuum or sweep up material and place into a suitable disposal container. Avoid generating dusty conditions.

**** SECTION 7 - HANDLING and STORAGE ****

Handling:

Avoid breathing dust, vapor, mist, or gas. Avoid contact with skin and eyes.

Storage:

Store in a cool, dry place. Store in a tightly closed container.

**** SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION ****

Engineering Controls:

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

Personal Protective Equipment

Eyes:

Wear chemical goggles.

Skin:

Wear appropriate protective gloves to prevent skin exposure.

Clothing:

Wear appropriate protective clothing to prevent skin exposure.

Respirators:

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

**** SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ****

Physical State:	Crystals
Color:	white - light beige
Odor:	Not available.
pH:	Not available.
Vapor Pressure:	Not available.
Viscosity:	Not available.
Boiling Point:	246 deg C @ 760 mmHg
Freezing/Melting Point:	113 - 116 deg C
Autoignition Temperature:	Not available.
Flash Point:	132 deg C (269.60 deg F)
Explosion Limits, lower:	Not available.
Explosion Limits, upper:	Not available.
Decomposition Temperature:	
Solubility in water:	0.3 g/l (20°C)
Specific Gravity/Density:	
Molecular Formula:	C8H9ClO
Molecular Weight:	156.61

**** SECTION 10 - STABILITY AND REACTIVITY ****

Chemical Stability:

Stable. Stable under normal temperatures and pressures.

Conditions to Avoid:

Incompatible materials.

Incompatibilities with Other Materials:

Strong oxidizing agents, strong bases.

Hazardous Decomposition Products:

Hydrogen chloride, carbon monoxide, carbon dioxide.

Hazardous Polymerization: Has not been reported.

**** SECTION 11 - TOXICOLOGICAL INFORMATION ****

RTECS#:

CAS# 88-04-0: ZE6850000

LD50/LC50:

CAS# 88-04-0: Draize test, rabbit, eye: 100 mg Moderate; Oral,

mouse: LD50 = 1 gm/kg; Oral, rat: LD50 = 3830 mg/kg.
Carcinogenicity:
4-Chloro-3,5-dimethylphenol -
Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.
See actual entry in RTECS for complete information.

**** SECTION 12 - ECOLOGICAL INFORMATION ****

Ecotoxicity:
Fish: LC50: 0.77 mg/l; 96H;Daphnia: LC50: 7.7 mg/l; 48H;logPOW: 2.8
Other
Avoid entering into waters or underground water.

**** SECTION 13 - DISPOSAL CONSIDERATIONS ****

Dispose of in a manner consistent with federal, state, and local regulations.

**** SECTION 14 - TRANSPORT INFORMATION ****

IATA
No information available.
IMO
No information available.
RID/ADR
No information available.

**** SECTION 15 - REGULATORY INFORMATION ****

European/International Regulations
European Labeling in Accordance with EC Directives
Hazard Symbols: XN
Risk Phrases:
R 22 Harmful if swallowed.
R 36/38 Irritating to eyes and skin.
R 43 May cause sensitization by skin contact.
Safety Phrases:
S 24 Avoid contact with skin.
S 37 Wear suitable gloves.
WGK (Water Danger/Protection)
CAS# 88-04-0: No information available.
United Kingdom Occupational Exposure Limits

United Kingdom Maximum Exposure Limits

Canada
CAS# 88-04-0 is listed on Canada's DSL List.
CAS# 88-04-0 is not listed on Canada's Ingredient Disclosure List.
Exposure Limits
US FEDERAL
TSCA
CAS# 88-04-0 is listed on the TSCA inventory.

**** SECTION 16 - ADDITIONAL INFORMATION ****

MSDS Creation Date: 7/16/1996 Revision #1 Date: 6/18/2001

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

ISSA'S GUIDE TO THE REGULATION OF ANTIBACTERIAL HAND SOAPS

Prepared by: Dan Wagner
Manager of Regulatory Compliance
International Sanitary Supply Association

I. **Introduction**: Antibacterial hand soap regulation is designed to ensure that these products are safe and effective when applied to human skin.

A. "Drugs": Antibacterial hand soaps are drugs as defined by § 201(g) of the Federal Food, Drug & Cosmetic Act (FFDCA). They are categorized as drugs because they are intended and labeled for topical antimicrobial use to prevent disease in humans. Therefore, they are regulated by the Food & Drug Administration (FDA) as over-the-counter (OTC) drugs. In accordance with the provisions of the FFDCA.

Antibacterial products that fall under the jurisdiction of FDA include all hand soaps, dips, and alcohol based washes for use when water is not available, also known as instant hand sanitizers.

The fact that they are designated as such triggers certain responsibilities. They include:

1. Registering with FDA as a drug establishment pursuant to 21 CFR § 207.20.

   a. Owners and operators of all drug establishments, including foreign establishments, *must* register by submitting Form FDA-2656. FDA will assign all registrants a permanent establishment number and a labeler code. Private label distributors are technically not required to *register*, but still must submit Form FDA-2656 to FDA in order to receive a labeler code.

   b. Drug establishment registration is used to capture information for the Drug Registration and Listing System (DRLS) database.

   c. Each drug establishment must renew its registration annually and within 30 days of receipt of Form FDA-2656e from FDA. Renewal forms are mailed by FDA according to an alphabetical schedule. (i.e.: Establishments whose names begin with A or B receive renewal forms in January, C, D and E, in February, etc.)

2. Listing the specific product as a drug pursuant to 21 CFR § 207.20.

a. Each establishment must also submit a drug listing for each drug product in commercial distribution, even if the product does not enter interstate commerce. Commercial distribution includes *any* distribution of a product other than for investigational purposes.

b. Drug listing is generally accomplished by submitting Form FDA-2657 to FDA. This form must be submitted at the same time as the initial establishment registration form (2656).

c. Private label distributors and foreign drug establishments must list all drug products. Private label distributors can list their products on their own or may rely on the manufacturer to do it for them.

   i. If a private label distributor will be listing its products on its own, he must provide a copy of Form FDA-2656 to the manufacturer to advise him that he will be responsible for listing with FDA. The distributor must then submit Form FDA-2657.

   ii. If the manufacturer will be listing the distributor's products on his behalf, the manufacturer must submit Form FDA-2658 and provide a copy to the distributor.

d. Drug listing information must be updated biannually, at the end of June and the end of December. Changes in formulation, labeling, packaging, or manufacturing are to be reported to FDA as soon as possible, however.

e. Sample completed forms (FDA-2656, 2657 and 2658) are available from FDA by calling 301-594-1086.

3. Complying with "Good Manufacturing Practices," (21 CFR § 211) the standards designed to ensure that safety and effectiveness is not sacrificed during the manufacturing process. This includes regulations regarding:

   a. Quality control
   b. Adequate buildings and facilities (lighting, ventilation, heating, sewage, sanitation)
   c. Appropriate design, cleaning and maintenance of equipment.
   d. Record keeping in the areas of production, distribution, quality control and customer complaints.
   e. Companies must also have an appropriate written procedure regarding their quality control.

4. Subjecting themselves to periodic inspection by FDA

B. Lawfully marketing and selling antibacterial hand soaps

Companies that wish to market and sell antibacterial hand soaps and sanitizers must comply with all specific regulations issued by FDA. Simply put, these products *must* be approved by FDA before they are marketed and sold. There are two ways to get a product approved.

1. * Way # 1: Product included in the OTC Drug Review and listed in the FDA Monograph.

2. * Way # 2: Completion and submission of a New Drug Application.

Both of these ways are discussed in greater detail below.

II. OTC Drug Review and Listing in the "Topical Antimicrobial Drug Product Monograph"

Introduction: The preferable way of obtaining FDA approval is through the OTC Drug Review and Monograph process. Products containing certain active ingredients will be able to avoid the extensive testing requirements of a new drug application, if FDA, after the OTC Drug Review, determines that they are generally safe and effective. The ingredients will then be listed in the future final monograph. The final monograph will contain a comprehensive list of acceptable ingredients, as well as testing and labeling requirements. FDA is currently conducting the Review and industry is awaiting the final monograph.

A. Introduction to the Monograph and OTC Drug Review Process

1. The OTC Drug Review and Monograph process was started because of FDA's concern with over-the-counter drug products that had been on the market for years prior to the passing of laws requiring proof of safety and effectiveness.

2. FDA is, therefore, establishing Monographs for each class of drug products.

3. The Drug Review and Monograph process is specifically handled by the Center of Drug Evaluation & Research's Division of Over-the-Counter Drug Products in the Office of Drug Evaluation. They are assisted by an advisory committee, the Nonprescription Drug Advisory Committee.

4. Monographs are "recipe books," listing acceptable ingredients, doses and formulations. They also include specific labeling requirements and testing provisions. Monographs can be updated as needed, with the addition of ingredients.

B. Monographs are issued in three stages:

1. Proposed
2. Tentative
3. Final

Note: While all three documents contain provisions that can offer significant guidance to industry, technically only the *final* monograph is legally enforceable. Therefore, prior to the final monograph's issuance, FDA will only initiate enforcement action in cases where there is an evident public safety concern.

C. The OTC Drug Review: After FDA publishes a proposed monograph, the Center for Drug Evaluation & Research begins analyzing the safety and effectiveness of products in the OTC Drug Review. Such a review is currently ongoing and the results of this review will form the basis for the ingredients listed as safe and effective in the final monograph.

D. Products eligible for the review: Only products having the same formulation, labeling and dosage as those that existed in the marketplace on or before December 4, 1975 are eligible for the Drug Review. All hand sanitizers included in the Review require a water rinse followed by drying except: "instant hand sanitizers" and certain USDA authorized hand dips used in the food processing industry.

FDA has divided all the active ingredients that are in the Review into three categories. These categories indicate whether the product can be lawfully marketed and sold while industry is waiting for the final monograph. Please review "Appendix A" for a full listing of the ingredients that are included in the Review. "Appendix A" also indicates the ingredient's designated category.

1. Category 1: Those ingredients that are listed in Category 1 have been determined to be safe and effective by FDA. Products containing these ingredients can be marketed and sold lawfully.

2. Category 2: Ingredients listed as Category 2 cannot be marketed and sold because FDA has determined that they are not safe and effective.

3. Category 3: Contains those ingredients for which FDA has declared there is insufficient evidence to determine whether they are safe and effective. FDA is not, however, presently objecting to the marketing and sale of products containing these active ingredients.

Note: FDA may still make a determination that these ingredients are not safe and

effective and choose *not* to include them in the final monograph.

Note: Triclosan is currently listed as a Category 3 ingredient. This is due to CDER's perceived lack of in vivo data to support existing in vitro data. Specifically, data is needed on the germicidal activity of the vehicle alone.

E. Antibacterial Hand soaps are part of the "Topical Antimicrobial Drug Product Monograph" under Subpart E: Heading: "Health Care Antiseptic Drug Products."

In June of 1994, FDA issued a tentative monograph that applies to all antibacterial hand soaps. The tentative monograph contains most of the provisions that can be expected to be included in the final monograph, whenever it is issued. When the final monograph is published, companies involved with hand soaps will have to comply with *all* provisions.

Generally the monograph defines a health care antiseptic drug product as an: "antiseptic containing drug product applied topically to the skin to help prevent infection of to help prevent cross-contamination."

These products are divided into three "product categories."

1. Antiseptic Hand Wash or Health Personnel Hand Wash

   Most general antibacterial hand soaps will fall into this category. Specifically, any product falling under the definition: "antiseptic containing preparation designed for frequent use, reduces the number of transient microorganisms on intact skin to a baseline level after adequate washing, rinsing and drying; it is broad spectrum, fast acting and, if possible, persistent."

   FDA has already determined that alcohol 60-95% in an aqueous solution and povidone iodine 5-10% are safe and effective when used for this purpose.

2. Patient Preoperative Skin Preparation

   Defined by the tentative monograph as: "fast acting, broad spectrum and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on skin."

   FDA has determined that the following active ingredients are safe and effective and, therefore, acceptable:

   a. Alcohol 60-95% in an aqueous solution
   b. Iodine Tincture U.S.P.

c. Iodine Topical Solution U.S.P.
d. Isopropyl alcohol 70-91.3% by volume in an aqueous solution
e. Povidone iodine 5-10%

3. Surgical Hand Scrub Drug Product

Includes all products falling under the definition: "an antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin and is broad spectrum, fast acting and persistent."

Currently, alcohol 60-95% in aqueous solution and povidone iodine 5-10% are considered safe and effective by FDA.

Labeling: The tentative monograph also contains labeling requirements. These labeling provisions are expected to be included in the final monograph and, therefore, must be complied with.

There are general labeling requirements that apply to all three product categories:

1. Every label must include a statement of identity. Each product should be identified as an antiseptic and/ or with the appropriate statement of identity for the specific category. The product label should also include the established name of the drug.

   Note: Although antiseptic, antimicrobial and antibacterial essentially all mean the same thing, antiseptic is the preferred term and is required to be included on the label.

2. Every label must include appropriate indications and directions for use.

3. Every label must include applicable warnings

   Examples of warnings: "For external use only"
   "Do not use in eyes"
   "Discontinue use if redness or irritation develops"
   "Flammable, keep away from fire or flame"

   Note: "Descriptive statements" are not regulated by the labeling provisions of the monograph. If the statement does not speak to the safety or effectiveness of the product it is not governed by the monograph. Examples of descriptive statements include: "Contains antibacterial ingredients," or "For purposes of promoting good hygiene."

   "Antibacterial" and "Antimicrobial" should *not* be used as indications on the label.

4. The monograph also contains various labeling provisions that apply

specifically to a particular product category under certain circumstances

a. Labeling pertaining to the directions of use

i. Category 1: Products to be used with water. "Wet hands and forearms. Apply 5 mililiters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for (applicable time). Rinse and repeat."

ii. Category 1: Products to be used without water: "Place a palmful (5 grams) of product in one hand. Spread on both hands and rub into the skin until dry (1-2 min.). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist and rub into the skin until dry."

b. Labeling pertaining to indications

i. Category 1 products may note on the label: "For handwashing to decrease bacteria on the skin before contact with a person under medical care" or "Recommended for repeated use."

ii. Category 2 products may include on the label: "For preparation of the skin prior to surgery" and for those that include alcohol: "For preparation of the skin prior to injection."

iii. Category 3 product labels may note: "Significantly reduces the number of microorganisms on the hands/ forearms prior to surgery or patient care."

Testing: The final monograph will include a list of active ingredients that are presumed safe and effective when used for a specific purpose, but products containing a listed ingredient will still be required to undergo testing prior to being placed on the market. The testing provisions in the monograph are detailed and specific and include a clinical study requirement. Generally, the necessary testing is designed to test the safety and effectiveness of the product.

1. Product must undergo both in vitro and in vivo testing.

   a. In vivo testing must be conducted on the final product.
   b In vitro testing must be conducted on the antiseptic ingredient, the vehicle and the final product.

2. Testing must be conducted for both positive and negative organisms as well as yeast.

3. Testing must be conducted on how quickly the drug product achieves its antimicrobial effect.

F. Lawfully Marketing and Selling Antimicrobial Hand Soaps Under the FDA Drug Review and Monograph Process: Checklist

As mentioned, the FDA Drug Review and Monograph process is the preferable manner in which to have antimicrobial hand soaps approved by FDA. Furthermore, unless a product is approved by FDA, it cannot be lawfully marketed and sold.

The following checklist provides a quick analysis of whether a product can be legally marketed and sold through the monograph process:

1. *Is the active ingredient included in the FDA OTC Drug Review?*

More specifically, did the "product" exist in the marketplace in the same formulation and dosage on or before December 4, 1975?

If the answer is yes, the product is probably included in the Review and, therefore, is eligible for inclusion as an "approved" product in the final monograph. All products included in the review are listed along with their ingredient categories in Appendix A.

Until the final monograph is issued, all ingredients listed as category I or III are considered "approved" by FDA. Please note that FDA, through the Drug Review, reserves the right to determine that a listed ingredient is *not* safe and effective and, therefore, is not approved as an antibacterial hand soap.

2. *Is the product labeled and intended for the same usage?*

For the product to be approved, the active ingredient had to have existed in the marketplace prior to December 4, 1975, and had to also have been used for the exact same purpose. For example, if Triclosan was used as a general antibacterial hand soap before that date, it can be used as a general antibacterial hand soap now. It could not, however, be used as a patient preoperative skin preparation under these circumstances because its intended use differs.

3. *Is the product labeled in accordance with the provisions of the tentative monograph?*

4. *Has the final product formulation been tested for safety and effectiveness prior to marketing in conjunction with the monograph's testing*

requirements?

5. *Have all "drug" requirements, including registering as a drug establishment, listing as a drug product, and following Good Manufacturing Practices been complied with?*

***If the answer to each of the above questions is "yes," and antibacterial hand soap may presently be marketed and sold in conjunction with the FDA Drug Review and Monograph process.

III New Drug Applications (NDA)

Introduction: If a product is not eligible for the Drug Review and, therefore, cannot be listed in the monograph, a new drug application must be submitted in accordance with the provisions of the Federal Food, Drug & Cosmetic Act (Section 505). FDA will carefully review the new formulation and product to determine if it is safe and effective when used as intended. If ruled safe and effective, the new drug application will be approved and the product can be lawfully placed on the market.

1. Approved products are listed in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations." This is also known as the "Orange Book" and is published annually with monthly supplements.

2. The Orange Book is available at the CDER/FDA web site, from the Superintendent of Documents/Government Printing Office, or the National Technical Information Service.

A. Application Process: A full application form must be signed and submitted pursuant to 21 CFR § 314. It will then be reviewed by the FDA Institutional Review Board in accordance with the following policies:

1. The Board will have 180 days to review the information submitted and reach a decision regarding approval or denial of the application.

2. Applications shall be denied in cases where the submitted data is insufficient to determine whether the product is safe and effective.

3. End of Review Meeting: At the conclusion of FDA's review of an application, applicants will have the opportunity to meet with the agency's reviewing official to discuss the denial of an application. Notice of the meeting should also be given to manufacturers and distributors of similar drug products.

B. The Application: Applicants must include a myriad of information in a new drug application. Essentially, FDA requires the submission of all information and data relevant to the safety and effectiveness of the new product.

An application for a new drug product will generally contain: (1) an application form; (2) an index; (3) a summary; (4) five or six technical sections; (5) case report tabulations of patient data; (6) case report forms; (7) drug samples; and (8) sample labeling.

1. Application form: Must include:

   a. The name and address of the applicant
   b. The name of the drug product, including its established, code, proprietary, and chemical names
   c. The dosage form and strength
   d. The route of administration
   e. The drug product's proposed indications for use.
   f. Various additional statements are required in accordance with Section 5 of the FFDCA.

2. Summary: An application is required to contain a summary of the application in enough detail that the reader may gain a good general understanding of the data and information contained within, including an understanding of the quantitative aspects of the submitted data.

   The summary must also include the proposed text of the labeling and individual summaries of the other sections of the application, including all technical sections.

3. Technical sections: Each technical section is required to contain data and information in sufficient detail to permit the agency to make an informed decision about approving the application.

   a. Chemistry, manufacturing and controls section: Must describe the composition, manufacture and specification of the drug, including all physical and chemical characteristics of the drug.

   b. Nonclinical pharmacology and toxicology section: Describing, with the aid of tables and graphs, animal and in vitro studies.

   c. Human pharmacokinetics and bioavailability section

   d. Clinical data section: Must describe the clinical investigations.

   e. Statistical section: Including a statistical evaluation of the clinical data.

   f. Pediatric use section: Describing the investigations of the drug on pediatric populations.

***_Note_: Products *cannot* be marketed or sold pending the approval of a new drug application.

C. Labeling: Products approved pursuant to a new drug application must be labeled in accordance with the Federal Food, Drug & Cosmetic Act (21 CFR § 201). Generally, each statement proposed on the label must be justified by the submitted efficacy data. Specifically, the label must contain the following elements:

1. Principal Display Panel: The label must include a central information panel that includes a statement of identity (established name of the drug) and a declaration of net quantity.

2. The "outside container of wrapper" should include the following information (in the order listed):

a. Drug Facts
b. Active Ingredient (the established name and the quantity of each active ingredient per dosage unit)
c. Purposes (principal intended action of the drug)
d. Uses (Indications)
e. Warnings

I.e.: "For External Use Only"
Allergic Reaction Warnings
Flammability Warnings

f. Directions For Use
g. Other Information (as required by an applicable Monograph)
h. Inactive Ingredient Identification
i. "Questions?" or "Questions and Comments?" followed by a telephone number of a source to answer questions about the product.

3. The following information should also be included on the label:

a. The name and business of the distributor, manufacturer or packer
b. Dosage information and the route or method of administration
c. Lot number: Capable of yielding the complete manufacturing history of the product

d. The National Drug Code number is requested but not required

4. Format: The FDA requires that drug product labeling adhere to specific format requirements, including uppercase lettering, letter height, type size

and text bullet style. The format requirements can be found at 21 CFR § 201.66 (d).

D. Testing: Products approved by a new drug application must also undergo extensive testing. The required testing focuses on whether the product is safe and effective and includes both in vitro and animal studies. FDA has issued specific testing guidelines titled "Guidelines for the Format and Content of the Clinical and Statistical Sections of an Application." This document is available over the Internet at FDA's web site: http://www.fda.gov/cder/guidance/index.htm.

E. Skin Protectants and Barrier Creams

Recently, there has been a growth in the market for products that are placed on healthy human skin in order to protect it from harmful organisms, including hazardous chemicals, allergens, and pathogens. These products are preventive and attempt to act as a barrier. Like, antibacterial hand soaps, these products are drugs and must be approved by FDA before they are marketed or sold.

Skin protectants and barrier creams are regulated as new drugs by FDA and, therefore, a new drug application must be submitted and approved. This is the case even in situations where the active ingredient is included in the monograph, because the product's intended use differs from its intended use in the past. For example, if a *hand soap* containing Triclosan existed prior to December 4, 1975, it will be included in the Drug Review for purposes of acting as a *hand soap* only and future Triclosan *hand soaps* may be approved through the monograph. However, if the manufacturer thereafter produces a *skin protectant* with Triclosan, it must be approved pursuant to a new drug application and cannot rely on the inclusion in the Drug Review and possible listing in the monograph.

Recently, Bristol Myers Squibb was sent a warning letter by FDA with regards to the Keri Antibacterial Hand Lotion. FDA specifically noted that skin barrier products lie outside the scope of the tentative monograph and that there is no evidence that topical antimicrobials were used as skin protectants prior to the start of the Drug Review. FDA maintains that they are unaware of any data showing that these products are safe and effective when used as intended.

IV Petitioning FDA for Inclusion in FDA Drug Review and Monograph

Introduction: If a product is not eligible for inclusion in the FDA Drug Review and Monograph, because it did not exist on or before December 4, 1975, a company can petition FDA and request that it be added to the list. If it is added, it will be reviewed by CDER for safety and effectiveness and if it is determined to be safe and effective it will be listed in the future final monograph.

Once the final monograph is published and ingredients are listed, the only way to be added to the list is to submit a petition.

A. Petitioning FDA should be done in accordance with 21 CFR § 10.30: Citizen's Petitions.

B. The petition should include a statement of the action requested and a statement of grounds.

C. Petitioners should include all clinical data relating to the safety and effectiveness of the product. All chemical information should also be submitted.

D. Example: USDA authorized products that were introduced after December 4, 1975.

Many hand cleaners and sanitizers were previously approved by USDA and included in the USDA "List of Proprietary Substances and NonFood Compounds." This included most sanitizers used in conjunction with food handling and preparation. USDA, however, discontinued its approval program in late1998 and will no longer approve or list products.

Despite previous USDA authorization and listing, products that were introduced into the marketplace after December 4, 1975 will have to be approved by FDA through the submission of a new drug application. Manufacturers, however, can attempt to bypass the new drug application by petitioning FDA to have the specific product which was previously approved by USDA included in the Drug Review.

V. FDA Enforcement

A. Warning letter is sent by FDA: FDA concerned with company's response. Did they offer to relabel the product? Did they offer to voluntarily pull the product off the market?

B. Seizure of Product: Recall of product only requested where there is a hazard associated with the product.

C. Injunction or Prosecution

1. Civil: monetary penalties may be assessed after the warning letter is sent and seizure of the product has occurred. Usually limited to prescription drugs.

2. Criminal penalties: can be instituted in cases where FDA determines that a violation is fraudulant or fragrant. Notice will be given to the company who will have the opportunity to show cause as to why criminal prosecution is improper. Notice will *not* be given in case where there is a perceived threat of fleeing or destruction of property.

VI. **Detergent Substances, Other than Soap, Intended for Use in Cleansing the Body**

Introduction: Detergent substances intended for cleansing the human body and which are not "soap" are regulated as cosmetics by FDA. As such these products are subject to 21 CFR § 701 et.al..

A. Designation of Ingredients: The labels of cosmetic products must contain the name of each ingredient in descending order of predominance except that fragrance may be listed as "fragrance." (21 CFR § 701.3)

B. Principal Display Panel: The principal display panel must be large enough to accommodate all the mandatory label information with "clarity and conspicuousness," and without obscuring designs, vignette, or crowding. The area of the panel must conform to the requirements of 21 CFR § 701.10.

C. Statement of Identity: The principal display panel must bear, as one of its principal features, a statement of identity of the product consistent with 21 CFR § 701.11.

D. Name and Address of the Manufacturer, Packer or Distributor: The label of a cosmetic product shall contain the name and place of business of the manufacturer packer or distributor in accordance with the particulars set forth in 21 CFR § 701.12.

E. Declaration of the Net Quantity of Contents: The label of a cosmetic in package form shall bear a declaration of a net quantity of content. The content shall be expressed in terms of weight, measure, numerical count or a combination thereof. The declaration of the net quantity of contents must conform to 21 CFR § 701.13.

VII. **Soap**

A. Definition: In implementing the Federal Food, Drug & Cosmetic Act, FDA interprets the term "soap to apply to products that meet the following two conditions:

1. The bulk of the non-volatile material in the product consists of an alkali salt of fatty acids and the detergent properties of the product are due to the alakli-fatty acid compounds; and

2. The product is labeled, sold and represented only as soap.

B. Regulations: Soap is ***not*** regulated by the FDA. Soap may be subject to one of the following requirements:

1. CPSC Regulations: Soap intended for sale to general consumers may be

regulated as "hazardous" and may be subject to the Consumer Product Safety Commission's (CPSC) precautionary labeling requirements set forth at 16 CFR § 1500.

2. OSHA Hazcom: Soap intended for sale to institutional users may be regulated as "hazardous" and may be subject to the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard. The OSHA Standard is codified at 29 CFR § 1910.1200.

3. Soaps not falling into any of the above categories which are targeted to consumer markets will generally be subject to the labeling regulations under Section 4 of the Fair Packaging and Labeling Act. The regulations implementing these provisions can be found at 16 CFR § 500 et.al..

APPENDIX A

Topical Antimicrobial Ingredients: Summary of Health-Care Antiseptic Active Ingredients

Active Ingredient	**Category Listing for an Antiseptic Handwash**	**Can Product be Lawfully Marketed?**
Alcohol 60-95 percent	I	Yes
Benzalkonium	III	Yes
Benzethonium	III	Yes
Chlorhexidine gluconate	N/A	No
Chloroxylenol	III	Yes
Cloflucarban	III	Yes
Florosalan	II	No
Hexachlorophene	II	No
Hexylresorcinol	III	Yes
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)	III	Yes

Iodine Active Ingredients	**Category Listing for an Antiseptic Handwash**	**Can Product be Lawfully Marketed?**
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)	III	Yes
Iodine Tincture U.S.P.	N/A	No
Iodine Topical Solution U.S.P.	N/A	No
Nonylphenoxypoly (ethyleneoxy) ethanoliodine	III	Yes
Poloxamer – iodine complex	III	Yes
Povidone iodine 5-10 percent	I	Yes
Undecoylium chloride iodine	III	Yes
Isopropyl alcohol 70-91.3 percent	III	Yes
Mercufenol chloride	N/A	No
Methylbenzethonium chloride	III	Yes
Phenol (less than 1.5 percent)	III	Yes
Phenol (greater than 1.5 percent)	II	No
Secondary amyltricresols	III	Yes
Sodium oxychlorosene	III	Yes
Tribromsalan	II	No
Triclocarban	III	Yes
Triclosan (not intended to be limited to use in bar soap)	III	Yes

Combinations	Category Listing for an Antiseptic Handwash	Can Product be Lawfully Marketed?
Calomel, oxyquinoline benzoate, triethanolamine, & phenol derivative	N/A	No
Mercufenol chloride and secondary amyltricresols in 50 percent alcohol	N/A	No
Triple Dye	N/A	No

N/A = Not applicable because not evaluated as an antiseptic handwash

GLUTARALDEHYDE
CASRN: 111-30-8

See Occupational Exposure Standards

Human Health Effects:

Evidence for Carcinogenicity:

A4; Not classifiable as a human carcinogen.
[American Conference of Governmental Industrial Hygienists. TLVs & BEIs: Threshold limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices for 2002. Cincinnati, OH. 2002.34]**QC REVIEWED**

Human Toxicity Excerpts:

WATER SOLNS OF ... GLUTARALDEHYDE ... ARE RELATIVELY STRONG IRRITANTS TO THE SKIN OR EYES. THEIR LOWER VAPOR PRESSURES, HOWEVER, REDUCE THE LIKELIHOOD THAT INHALATION WOULD BE A SUBSTANTIAL ROUTE OF EXPOSURE.
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994. 311]**PEER REVIEWED**

...SEVERE EYE, PLUS NOSE & THROAT IRRITATION WERE FELT BY OPERATOR & INVESTIGATORS /IN COLD-STERILIZING PROCEDURE/, WHO ALSO EXPERIENCED SUDDEN HEADACHE.
[American Conference of Governmental Industrial Hygienists. Documentation of the Threshold Limit Values for Substances in Workroom Air. Third Edition, 1971. Cincinnati, Ohio: American Conference of Governmental Industrial Hygienists, 1971. (Plus supplements to 1979)447]**PEER REVIEWED**

IT CAN...CAUSE SENSITIZATION (ALLERGIC CONTACT DERMATITIS) FROM OCCASIONAL OR INCIDENTAL OCCUPATIONAL EXPOSURE.
[American Conference of Governmental Industrial Hygienists. Documentation of the Threshold Limit Values for Substances in Workroom Air. Third Edition, 1971. Cincinnati, Ohio: American Conference of Governmental Industrial Hygienists, 1971. (Plus supplements to 1979)447]**PEER REVIEWED**

Nine medical and nursing staff (4 male, 5 female) working in a endoscopy unit (with 2% glutaraldehyde on the disinfecting trolley) were offered a questionnaire to determine the symptoms associated with glutaraldehyde. Eight members of the staff (3 male, 5 female), who had been affected by the vapor, underwent clinical assessment, including details of any history of atopy. None of the staff affected had any previous history of allergy. Air samples obtained by a personal sampler over a period of 1 hr, from the breathing zone of the nurse carrying a cold sterilization process, contained 0.12 ppm glutaraldehyde. Air at the corridor bench contained 0.05 ppm. Clinical manifestations included watering of eyes, rhinitis, dermatitis, respiratory difficulty, nausea and headache.
[Jachuck SF et al; J Soc Occup Med 39 (2): 69-71 (1989)]**PEER REVIEWED**

Although glutaraldehyde is a weak allergen, the vapors from glutaraldehyde may act as an irritant to bronchial & laryngeal mucous membranes, & prolonged exposure could produce localized edema & other symptoms suggestive of an allergic response.
[Sullivan, J.B. Jr., G.R. Krieger (eds.). Hazardous Materials Toxicology-Clinical Principles of Environmental Health. Baltimore, MD: Williams and Wilkins, 1992. 983]**PEER REVIEWED**

In a study simulating a complete cold sterilizing procedure lasting 12 min, the integrated sample of activated, 2% aqueous sol resulted in 0.38 ppm of glutaraldehyde measured at the operator's breathing zone. Although some irritation was recorded throughout this procedure, it was not until the end of the operation, when the equipment undergoing sterilization was being air-hose dried, that severe irritation of the eye, nose, and throat was experienced by the operator and by the investigators, who also experienced sudden headaches.
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.703]**PEER REVIEWED**

A 33 year old respiratory technologist developed occupational asthma as a result of exposure to glutaraldehyde. The case was documented by preshift and postshift spirometry, appropriate changes in peak expiratory flow rate, provocative concentration causing a 20% fall in forced expiratory volume in 1 second, and workplace challenge test. The subject had a history of asthma as a child with mild symptoms, readily relieved by bronchodilators. As an adult, she had symptoms briefly following colds. At age 29 she began working in a bronchoscopy unit at a local hospital; her asthma worsened since that time and she was using an albuterol inhalant three to four times a day. The subject also intermittently received courses of prednisone for acute exacerbations. The subject assisted physicians in fiberoptic bronchoscopy and also cleaned bronchoscopes after use with Sporicidin which contained 3.6% glutaraldehyde, 7% phenol, and 1.2% sodium-phenolate. Cleaning was performed in a small room with no ventilation. Sporicidin was placed in a basin that was not covered during cleaning. After diagnosis, the subject continued work but no longer performed the cleaning operation. As a result, her symptoms have decreased and she has been able to gradually reduce the dose of inhaled beclomethasone to 500 ug/day without recurrence. Lung function tests have returned to normal levels.
[Chan-Yeung M et al; Journal of Allergy and Clinical Immunology 91 (5): 974-8 (1993)]**PEER REVIEWED**

This letter reports two cases of work-related asthma in radiographers, each case attributable to a different agent. Tests on one patient revealed an asthmatic response on exposure to glutaraldehyde, a hardener used during developing, while tests on the other showed adverse reactions to fixative chemicals. Although it is likely that, under the best conditions, concentrations of glutaraldehyde in radiographic departments are below the occupational exposure standard, higher levels may occur during maintenance or where ventilation is inadequate. Concern about respiratory disease has been expressed within the radiography profession.
[Cullman P et al; Lancet 340 (8833): 1477 (1992)]**PEER REVIEWED**

A case of contact allergic dermatitis due to occupational exposure to benzalkonium chloride and glutaraldehyde in a dental nurse was described. A 36 year old female dental nurse with an intensely itchy eczena on her hands, forearms, upper arms, and face was examined. The eczema

began on her hands and forearms 4 months previously and gradually spread to her upper arms and face. She was patch tested with the standard Italian allergen series, a nurse series, and products she used at work. She reacted to thiuram mix and nickel sulfate in the standard series, glutaraldehyde and benzalkonium chloride in the nurse series, and three products she used at work (Sanipull, Ster-l, and Cidex). Sanipull contained 1% benzalkonium chloride, Ster-l contained glutaraldehyde, and Cidex contained 2% acidic glutaraldehyde. The reactions to benzalkonium chloride and glutaraldehyde and the products containing these were judged to reflect her current symptoms. The reactions to nickel sulfate and thiuram mix were judged to reflect episodes of contact dermatitis induced by jewelry and latex rubber gloves. /It was/ concluded that cases like this can be expected to become more common since benzalkonium chloride and glutaraldehyde are being used more frequently to sterilize dental and other medical instruments and equipment.
[Cusano F, Luciano S; Contact Dermatitis 28 (2): 127 (1993)]**PEER REVIEWED**

Proctitis has been reported after the use of glutaraldehyde as a disinfectant of flexible sigmoidoscopes. Within hours of an exam patients may have acute tenesmus & bloody diarrhea. The prognosis is good. Recovery follows in a few weeks.
[Ellenhorn, M.J., S. Schonwald, G. Ordog, J. Wasserberger. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. 2nd ed. Baltimore, MD: Williams and Wilkins, 1997. 1219]**PEER REVIEWED**

Skin, Eye and Respiratory Irritations:

A severe skin and eye irritant in humans.
[Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 1734]**PEER REVIEWED**

Contact with liquid causes severe irritation of eyes and irritation of skin.
[U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.]**PEER REVIEWED**

Eye and respiratory irritation are noted at a level of 0.3 ppm.
[Ellenhorn, M.J., S. Schonwald, G. Ordog, J. Wasserberger. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. 2nd ed. Baltimore, MD: Williams and Wilkins, 1997. 1219]**PEER REVIEWED**

Drug Warnings:

This disinfectant may cross-react with formaldehyde.
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 1620]**PEER REVIEWED**

Probable Routes of Human Exposure:

Occupational exposure to health care workers is common.
[Sullivan, J.B. Jr., G.R. Krieger (eds.). Hazardous Materials Toxicology-Clinical Principles of Environmental Health. Baltimore, MD: Williams and Wilkins, 1992. 983]**PEER REVIEWED**

Sensitization has occurred mainly through its use as a cold sterilizing solution in hospitals and dental clinics where medical and allied professionals including x-ray film handlers may be exposed to activated glutaraldehyde in concentrations of 0.13-2%.
[Sullivan, J.B. Jr., G.R. Krieger (eds.). Hazardous Materials Toxicology-Clinical Principles of Environmental Health. Baltimore, MD: Williams and Wilkins, 1992. 983]**PEER REVIEWED**

Minimum Fatal Dose Level:

3-4. 3= MODERATELY TOXIC, PROBABLE ORAL LETHAL DOSE (HUMAN) 0.5-5 G/KG, BETWEEN 1 OUNCE & 1 PINT FOR 70 KG PERSON (150 LB). 4=VERY TOXIC, PROBABLE ORAL LETHAL DOSE (HUMAN) 50-500 MG/KG, BETWEEN 1 TEASPOON AND 1 OUNCE FOR 70 KG PERSON (150 LB).
[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-187]**PEER REVIEWED**

Emergency Medical Treatment:

Emergency Medical Treatment:

EMT Copyright Disclaimer:

The following Overview, *** GLUTARALDEHYDE ***, is relevant for this HSDB record chemical.

Life Support:

- This overview assumes that basic life support measures have been instituted.

Clinical Effects:

SUMMARY OF EXPOSURE

0.2.1.1 ACUTE EXPOSURE

- Glutaraldehyde may be irritating to the eyes, skin, and mucous membranes. Exposure may induce asthma in some individuals and can cause an allergic contact dermatitis.
- Vapor exposure in humans has been associated with coryza, epistaxis, headache, asthma, chest pain, palpitations, tachycardia, and nausea and vomiting.
  1. Additional symptoms from exposure may include cough, rhinitis, respiratory difficulty, and lacrimation.
- Human exposure data are minimal. Symptoms and treatments may be similar to that of formaldehyde and are dependent on route and concentration of exposure.

- CNS depression has occurred in experimental animals given intravenous injections.

HEENT

0.2.4.1 ACUTE EXPOSURE

- Topical glutaraldehyde has caused severe eye injury in rabbits. A 2% solution may cause severe inflammation, lacrimation, and edema.
- Glutaraldehyde is particularly irritating to the nose and throat.

CARDIOVASCULAR

0.2.5.1 ACUTE EXPOSURE

- Tachycardia has been reported with occupational exposures (dermal and inhalation). Hypotension has been reported with formaldehyde and may be a concern with glutaraldehyde.

RESPIRATORY

0.2.6.1 ACUTE EXPOSURE

- Occupational asthma has been reported following inhalation. It is delayed in onset.
- Hemorrhagic pulmonary congestion and pneumonitis were common effects reported in animals regardless of whether glutaraldehyde was administered IV, orally, or by inhalation.

NEUROLOGIC

0.2.7.1 ACUTE EXPOSURE

- Seizures and CNS depression were noted in animals given intravenous glutaraldehyde.

GASTROINTESTINAL

0.2.8.1 ACUTE EXPOSURE

- Glutaraldehyde may cause irritation of the gastrointestinal tract and frank gastrointestinal hemorrhages in higher concentrations. Sigmoidoscopy instruments disinfected with glutaraldehyde and inadequately rinsed may cause bloody diarrhea and proctitis.

DERMATOLOGIC

0.2.14.1 ACUTE EXPOSURE

- Dermal solutions of 2% to 10% are used therapeutically, but may result in staining of skin and nails a brown or golden brown color. A 10% solution is a potential skin irritant and has caused pruritus and dermatitis. Allergic contact dermatitis has also been reported.

CARCINOGENICITY

0.2.21.2 HUMAN OVERVIEW

- At the time of this review, no studies were found on the possible carcinogenic activity of glutaraldehyde in humans.
- Nasal cancers have been reported in rat inhalational studies.

0.2.21.3 ANIMAL OVERVIEW

- NASAL CANCERS - Glutaraldehyde was tested against the known rat nasal carcinogen, formaldehyde, and found to be 5 times as potent as formaldehyde. Preliminary data suggest that a chronic inhalation study is needed to assess the carcinogenic potential of glutaraldehyde (St Clair et al, 1989).

- Glutaraldehyde was not carcinogenic in rats or mice by inhalation in a 13-week exposure.

GENOTOXICITY

- Glutaraldehyde, in a dentin bonding agent, has been shown to be mutagenic in an Ames assay using Salmonella typhimurium strains (RTECS, 2001; Schweikl et al, 1994) as well as in sister chromatid exchange and mutations in mouse lymphocyte cells and cytogenetic changes in hamster ovary cells (RTECS, 2001).

Laboratory:

- Blood gases or bicarbonate levels should be monitored for possible development of acidosis. Liver function tests should be monitored.
- If respiratory tract irritation or respiratory depression are clinically evident, consider monitoring pulse oximetry, arterial blood gases, chest x-ray, and pulmonary function tests.

Treatment Overview:

SUMMARY EXPOSURE

- The treatment of glutaraldehyde is nearly identical to that of formaldehyde. It appears to be slightly less toxic except for intravenous or ocular exposures. Because of its lower vapor pressure, glutaraldehyde is less likely to be inhaled. Treatment should be aimed at recognition and management of gastrointestinal hemorrhage, ulceration and perforation, and any systemic effects such as CNS depression and hypotension.

ORAL EXPOSURE

- SUMMARY - Glutaraldehyde treatment is nearly identical to formaldehyde. It appears to be slightly less toxic except for IV and ocular exposures. Treatment: observe for and manage any gastrointestinal hemorrhage, ulceration, or perforation; supportive care is indicated for CNS depression and hypotension.
- DILUTION: Immediately dilute with 4 to 8 ounces (120 to 240 mL) of milk or water (not to exceed 4 ounces/120 mL in a child).
- Because of the potential for gastrointestinal tract irritation or CNS depression and subsequent aspiration, do NOT induce emesis. Significant caustic injury burns may occur following ingestion. The possible benefit of early removal of some ingested material by cautious gastric lavage must be weighed against its potential complications such as bleeding or perforation or aspiration.
- ACTIVATED CHARCOAL: Administer charcoal as a slurry (240 mL water/30 g charcoal). Usual dose: 25 to 100 g in adults/adolescents, 25 to 50 g in children (1 to 12 years), and 1 g/kg in infants less than 1 year old.
- HYPOTENSION: Infuse 10 to 20 mL/kg isotonic fluid, place in Trendelenburg position. If hypotension persists, administer dopamine (5 to 20 mcg/kg/min) or norepinephrine (0.1 to 0.2 mcg/kg/min), titrate to desired response.
- ESOPHAGOSCOPY - Should be considered following oral

ingestion of concentrated glutaraldehyde solutions to assess the severity of caustic injury.

INHALATION EXPOSURE

- Move patient to fresh air and monitor for respiratory distress. Hemorrhagic pneumonitis has been reported in animals exposed to glutaraldehyde.
- If respiratory tract irritation or respiratory depression is evident, monitor arterial blood gases, chest x-ray, and pulmonary function tests.

EYE EXPOSURE

- Exposed eyes should be irrigated copiously with water for at least 15 minutes. An ophthalmic examination should be considered if irritation or pain persists thereafter. Glutaraldehyde in concentrations as low as 2% may cause ocular damage (severe inflammation, lacrimation, and edema).

DERMAL EXPOSURE

- DECONTAMINATION: Remove contaminated clothing and wash exposed area thoroughly with soap and water. A physician may need to examine the area if irritation or pain persists.

Range of Toxicity:

- The toxic dose has not been established in man. Ten percent solutions have caused dermatitis when applied therapeutically. Two percent solutions have caused ocular damage.

[Rumack BH: POISINDEX(R) Information System. Micromedex, Inc., Englewood, CO, 2003; CCIS Volume 116, edition exp May, 2003. Hall AH & Rumack BH (Eds): TOMES(R) Information System. Micromedex, Inc., Englewood, CO, 2003; CCIS Volume 116, edition exp May, 2003.]**PEER REVIEWED**

Antidote and Emergency Treatment:

Skin that becomes contaminated with glutaraldehyde should be washed immediately or showered.

[Ellenhorn, M.J., S. Schonwald, G. Ordog, J. Wasserberger. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. 2nd ed. Baltimore, MD: Williams and Wilkins, 1997. 1219]**PEER REVIEWED**

Basic treatment: Establish a patent airway. Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Aggressive airway management may be necessary. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Anticipate seizures and treat if necessary ... . Monitor for shock and treat if necessary ... . Monitor for pulmonary edema and treat if necessary ... . For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with normal saline during transport ... . Do not use emetics. For ingestion, rinse mouth and administer 5 ml/kg up to 200 ml of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool. Administer activated charcoal ... . /Aldehydes and related compounds/

[Bronstein, A.C., P.L. Currance; Emergency Care for Hazardous Materials

Exposure. 2nd ed. St. Louis, MO. Mosby Lifeline. 1994.,p. 234-35]**PEER REVIEWED**

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious or in respiratory arrest. Intubation should be considered at the first sign of upper airway obstruction caused by edema. Positive pressure ventilation techniques with a bag-valve-mask device may be beneficial. Start an IV with D5W /SRP: "To keep open", minimal flow rate/. Use lactated Ringer's if signs of hypovolemia are present. Watch for signs of fluid overload. Treat seizures with diazepam ... . For hypotension with signs of hypovolemia, administer fluid cautiously. Consider vasopressors if patient is hypotensive with a normal fluid volume. Watch for signs of fluid overload ... . Consider drug therapy for pulmonary edema ... . Use proparacaine hydrochloride to assist eye irrigation ... . /Aldehydes and related compounds/
[Bronstein, A.C., P.L. Currance; Emergency Care for Hazardous Materials Exposure. 2nd ed. St. Louis, MO. Mosby Lifeline. 1994. 235]**PEER REVIEWED**

Animal Toxicity Studies:

Evidence for Carcinogenicity:

A4; Not classifiable as a human carcinogen.
[American Conference of Governmental Industrial Hygienists. TLVs & BEIs: Threshold limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices for 2002. Cincinnati, OH. 2002.34]**QC REVIEWED**

Non-Human Toxicity Excerpts:

IRRITANT EFFECT ON SKIN OF RABBITS IS MODERATE. /FROM TABLE/
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994. 312]**PEER REVIEWED**

... A 25% AQ SOLN ON RABBIT EYES, CAUSED SEVERE INJURY, GRADED 9 ON A SCALE OF 10. A 1% SOL QUICKLY ABOLISHES THE B-WAVE OF THE RABBIT RETINA IN VITRO.
[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986. 462]**PEER REVIEWED**

18 6-8 wk old male and female mice of various strains (Swiss, Balb/c, DBA/2, CBA, C57B1/6, and B6D2F1) received a topical application of 10% glutaraldehyde in ethanol on both sides of the right ear on days 0 and 2, and a scapular sc injection of 0.05 ml of complete Freunds adjuvant on day 2. On day 9, left ear thickness was measured immediately before topical application of 1% glutaraldehyde in ethanol, on both sides of the ear, and again 24 hr later (day 10). A statistically significant incr in ear thickness was seen.
[Descotes J; J Toxicol Cutan Ocular Toxicol 7 (4): 263-72 (1988)]**PEER REVIEWED**

Solutions of 1 and 2% glutaral destroy Bacillus anthracis spores more rapidly than 4% formaldehyde. ... In addition to sporicidal activity glutaral has inactivated enteroviruses and other viruses.

[Booth, N.H., L.E. McDonald (eds.). Veterinary Pharmacology and Therapeutics. 5th ed. Ames, Iowa: Iowa State University Press, 1982. 714]**PEER REVIEWED**

Alkanes, alcohols, ketones, and aldehydes reported not to produce neurotoxicity after chronic and subchronic exposures. Test substance: Glutaraldehyde, Species: Rat, Route: Water, Exposure conditions: 0.25, 0.5, and 1.0% in drinking water for 11 weeks. /From table/
[O'Donoghue, J.L. (ed.). Neurotoxicity of Industrial and Commercial Chemicals. Volume II. Boca Raton, FL: CRC Press, Inc., 1985. 81]**PEER REVIEWED**

Percutaneous lethal dose in rabbits 0.6 g/kg.
[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-187]**PEER REVIEWED**

... When mice were exposed at 8 and 33 ppm (33 and 133 mg/cu m) of alkalinized glutaraldehyde for 24 hr, the animals reacted with distinctly nervous behavior, panting and washing of the face and limbs, with symptoms disappearing after a few hours. Fifty percent of the mice in each group were sacrificed immediately postexposure, and the remaining animals were killed the following day. Lungs and kidneys showed no histopathologic damage, but the livers of the mice exposed at 33 ppm showed definite signs of toxic hepatitis, possibly reversible, since it was present to somewhat lesser degree in the animals necropsied one day postexposure.
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.703]**PEER REVIEWED**

... CONCLUSIONS: Under the conditions of these 2 yr inhalation studies, there was no evidence of carcinogenic activity of glutaraldehyde in male or female F344/N rats exposed to 250, 500 750 ppb. There was no evidence of carcinogenic activity in male or female B6C3F1 mice exposed to 62.5, 125 or 250 ppb.
[Toxicology & Carcinogenesis Studies of Glutaraldehyde in F344/N Rats and B6C3F1 Mice p.5 Technical Report Series No. 490 (1999) NIH Publication No. 99-3980 U.S. Department of Health and Human Services, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709]**PEER REVIEWED**

National Toxicology Program Studies:

... 2 yr study in rats: Groups of 50 male and 50 female F344/N rats were exposed to 0, 250, 500 or 750 ppb glutaraldehyde vapor by inhalation 6 hr/day 5 days/wk for 104 wk. ... 2 yr study in mice: Groups of 50 male and 50 female B6C3F1 mice were exposed to 0, 62.5, 125 or 250 ppb glutaraldehyde vapor by inhalation, 6 hr/day 5 days/wk for 104 wk. ... CONCLUSIONS: Under the conditions of these 2 yr inhalation studies, there was no evidence of carcinogenic activity of glutaraldehyde in male or female F344/N rats exposed to 250, 500 750 ppb. There was no evidence of carcinogenic activity in male or female B6C3F1 mice exposed to 62.5, 125 or 250 ppb.
[Toxicology & Carcinogenesis Studies of Glutaraldehyde in F344/N Rats and B6C3F1 Mice p.5 Technical Report Series No. 490 (1999) NIH Publication No. 99-3980 U.S. Department of Health and Human Services, National Toxicology

Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709]**PEER REVIEWED**

Non-Human Toxicity Values:

LD50 Rat oral 134 mg/kg
[Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 1734]**PEER REVIEWED**

LD50 Rabbit skin 2,560 mg/kg
[Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 1734]**PEER REVIEWED**

LD50 Rat oral 0.82 g/kg
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994. 312]**PEER REVIEWED**

LD50 Rabbit skin 0.64 ml/kg
[Clayton, G.D., F.E. Clayton (eds.) Patty's Industrial Hygiene and Toxicology. Volumes 2A, 2B, 2C, 2D, 2E, 2F: Toxicology. 4th ed. New York, NY: John Wiley & Sons Inc., 1993-1994. 312]**PEER REVIEWED**

LC50 Rat inhalation 5000 ppm/4 hr exposure
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.703]**PEER REVIEWED**

LD50 Rat oral 1.30 ml/kg 50% aqueous soln (w/w)
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LC50 Rat (male) inhalation 24 ppm/ 4 hr
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LC50 Rat (female) inhalation 40 ppm/ 4 hr
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat oral 1.87 ml/kg 25% aqueous soln (w/w)
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat oral 3.3 ml/kg 5% aqueous soln (w/w)
[American Conference of Governmental Industrial Hygienists, Inc.

Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat oral 12.3 ml/kg 1% aqueous soln (w/w)
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat oral 96.1 mg/kg 2% Cidex formulation
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Mouse oral 100 mg/kg
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Mouse oral 1300 mg/kg 25% olive oil soln
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Mouse (male) oral 122 mg/kg 2% Cidex formulation
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rabbit oral 1.59 ml/kg 50% aqueous soln (w/w)
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rabbit oral 8.0 ml/kg 25% aqueous soln (w/w)
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rabbit oral >16 ml/kg 5% aqueous soln (w/w)
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat sc 2390 mg/kg
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Mouse (male) sc 1430 mg/kg
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat ip 17900 ug/kg
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Mouse ip 13900 ug/kg
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat iv 15300 ug/kg
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Mouse iv 15400 ug/kg
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

LD50 Rat iv 9800 ug/kg
[Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 1734]**PEER REVIEWED**

Metabolism/Pharmacokinetics:

Metabolism/Metabolites:

... The probable major metabolic pathway /is/ initial oxidation to the corresponding mono- or dicarboxylic acid by aldehyde dehydrogenase & then further oxidation of the acidic intermediate to carbon dioxide.
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

Absorption, Distribution & Excretion:

Material balance & pharmacokinetic studies were conducted with rats & rabbits including iv or topical dosing with [14C]glutaraldehyde. IV dosing resulted in radiochemical recovery from 86% to 101%. Principal route of recovery was as CO2 at 22% to 80% of the admin dose (7%-28% urinary, 0.2%-5% feces). Epicutaneous dosing resutled in radiochemical recovery primarily in the skin at the site of application (31%-61%) with no consistent accumulation in any other tissue. Rabbits absorbed 33% to 53% of the epicutaneously administered dose & rats absorbed 4.1% to 8.7%. Pharmacokinetic studies indicated percutaneous radiochemical absorption of 0.3% to 2.1% for rats & 2.5% to 15.6% for rabbits under conservative study conditions that are likely to overestimate potential human exposure conditions.
[American Conference of Governmental Industrial Hygienists, Inc. Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. Volumes I, II, III. Cincinnati, OH: ACGIH, 1991.704]**PEER REVIEWED**

Mechanism of Action:

Cross-linking of the peptidoglycan in the bacterial cell wall with intermolecular bonding between techoic acid chains & glutaraldehyde may cause a partial sealing & contraction of the outer cell envelope.
[Ellenhorn, M.J., S. Schonwald, G. Ordog, J. Wasserberger. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. 2nd ed. Baltimore, MD: Williams and Wilkins, 1997. 1219]**PEER REVIEWED**

Pharmacology:

Therapeutic Uses:

Disinfectants; Fixatives
[National Library of Medicine's Medical Subject Headings online file (MeSH, 1999)]**PEER REVIEWED**

...USED ON LIVING TISSUES IN TREATMENT OF WARTS & HYPERHIDROSIS.
[American Medical Association, AMA Department of Drugs, AMA Drug Evaluations. 3rd ed. Littleton, Massachusetts: PSG Publishing Co., Inc., 1977. 894]**PEER REVIEWED**

Glutaral 2% in a buffered solution (pH 7.5) ... has an anhidrotic effect when applied to the palms and soles but not the axillae.
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 1213]**PEER REVIEWED**

IT...POSSESSES TUBERCULOCIDAL ACTION.
[American Medical Association, AMA Department of Drugs, AMA Drug Evaluations. 3rd ed. Littleton, Massachusetts: PSG Publishing Co., Inc., 1977. 894]**PEER REVIEWED**

Drug Warnings:

This disinfectant may cross-react with formaldehyde.
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 1620]**PEER REVIEWED**

Minimum Fatal Dose Level:

3-4. 3= MODERATELY TOXIC, PROBABLE ORAL LETHAL DOSE (HUMAN) 0.5-5 G/KG, BETWEEN 1 OUNCE & 1 PINT FOR 70 KG PERSON (150 LB). 4=VERY TOXIC, PROBABLE ORAL LETHAL DOSE (HUMAN) 50-500 MG/KG, BETWEEN 1 TEASPOON AND 1 OUNCE FOR 70 KG PERSON (150 LB).
[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984.,p. II-187]**PEER REVIEWED**

Environmental Fate & Exposure:

Probable Routes of Human Exposure:

Occupational exposure to health care workers is common.
[Sullivan, J.B. Jr., G.R. Krieger (eds.). Hazardous Materials Toxicology-Clinical Principles of Environmental Health. Baltimore, MD: Williams and Wilkins, 1992. 983]**PEER REVIEWED**

Sensitization has occurred mainly through its use as a cold sterilizing solution in hospitals and dental clinics where medical and allied professionals including x-ray film handlers may be exposed to activated glutaraldehyde in concentrations of 0.13-2%.
[Sullivan, J.B. Jr., G.R. Krieger (eds.). Hazardous Materials Toxicology-Clinical Principles of Environmental Health. Baltimore, MD: Williams and Wilkins, 1992. 983]**PEER REVIEWED**

Environmental Standards & Regulations:

FIFRA Requirements:

As the federal pesticide law FIFRA directs, EPA is conducting a comprehensive review of older pesticides to consider their health and environmental effects and make decisions about their future use. Under this pesticide reregistration program, EPA examines health and safety data for pesticide active ingredients initially registered before November 1, 1984, and determines whether they are eligible for reregistration. In addition, all pesticides must meet the new safety standard of the Food Quality Protection Act of 1996. Pesticides for which EPA had not issued Registration Standards prior to the effective date of FIFRA, as amended in 1988, were divided into three lists based upon their potential for human exposure and other factors, with List B containing pesticides of greater concern and List D pesticides of less concern. Glutaraldehyde is found on List B. Case No: 2315; Pesticide type: fungicide, antimicrobial; Case Status: OPP is reviewing data from the pesticide's producers regarding its human health and/or environmental effects, or OPP is determining the pesticide's eligibility for reregistration and developing the Reregistration Eligibility Decision (RED) document.; Active ingredient (AI): Glutaraldhyde; Data Call-in (DCI) Date(s): 06/10/91, 07/15/92, 10/13/95; AI Status: The producers of the pesticide has made commitments to conduct the studies and pay the fees required for reregistration, and are meeting those commitments in a timely manner.
[USEPA/OPP; Status of Pesticides in Registration, Reregistration and Special Review p.184 (Spring, 1998) EPA 738-R-98-002]**PEER REVIEWED**

TSCA Requirements:

Section 8(a) of TSCA requires manufacturers of this chemical substance to report preliminary assessment information concerned with production, use, and exposure to EPA as cited in the preamble in 51 FR 41329.
[40 CFR 712.30 (7/1/2000)]**PEER REVIEWED**

Pursuant to section 8(d) of TSCA, EPA promulgated a model Health and Safety Data Reporting Rule. The section 8(d) model rule requires manufacturers, importers, and processors of listed chemical substances and mixtures to submit to EPA copies and lists of unpublished health and

safety studies. Pentanedial is included on this list.
[40 CFR 716.120 (7/1/2000)]**PEER REVIEWED**

FDA Requirements:

Microcapsules for flavoring substances. Microcapsules maybe safely used for encapsulating discrete particles of flavoring substances that are generally recognized as safe for their intended use or are regulated under this part, in accordance with the following conditions: ... Component: glutaraldehyde; Limitation: as cross-linking agent for insolubilizing a coacervate of gum araabic and gelatin.
[21 CFR 172.230 (4/1/2000)]**PEER REVIEWED**

Glutaraldehyde is an indirect food additive for use only as a component of adhesives.
[21 CFR 175.105 (4/1/2000)]**PEER REVIEWED**

Chemical/Physical Properties:

Molecular Formula:

C5-H8-O2
PEER REVIEWED

Molecular Weight:

100.13
[Howard PH, Neal M; Dictionary of Chemical Names and Synonyms. Boca Raton, FL: Lewis Publishers, p. I-263 (1992)]**PEER REVIEWED**

Color/Form:

Colorless liquid
[Ashford, R.D. Ashford's Dictionary of Industrial Chemicals. London, England: Wavelength Publications Ltd., 1994. 450]**PEER REVIEWED**

Oil
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 761]**PEER REVIEWED**

Odor:

Pungent odor
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 152]**PEER REVIEWED**

Boiling Point:

188 deg C (decomp)
[Lide, DR (ed.). CRC Handbook of Chemistry and Physics. 81st Edition. CRC Press LLC, Boca Raton: FL 2000,p. 3-240]**PEER REVIEWED**

Melting Point:

FP: -14 deg C
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 13th ed. New York, NY: John Wiley & Sons, Inc. 1997. 541]**PEER REVIEWED**

Density/Specific Gravity:

0.72
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 13th ed. New York, NY: John Wiley & Sons, Inc. 1997. 541]**PEER REVIEWED**

Solubilities:

Miscible in ethanol and water; sol in benzene
[Lide, DR (ed.). CRC Handbook of Chemistry and Physics. 81st Edition. CRC Press LLC, Boca Raton: FL 2000,p. 3-240]**PEER REVIEWED**

SOL IN ETHER
[American Conference of Governmental Industrial Hygienists. Documentation of the Threshold Limit Values for Substances in Workroom Air. Third Edition, 1971. Cincinnati, Ohio: American Conference of Governmental Industrial Hygienists, 1971. (Plus supplements to 1979)447]**PEER REVIEWED**

Spectral Properties:

Index of refraction: 1.4338 @ 25 deg C
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 761]**PEER REVIEWED**

MASS: NIST 1116 (NIST/EPA/MCDC Mass Spectral Database 1990 Version)
[Lide, D.R., G.W.A. Milne (eds.). Handbook of Data on Organic Compounds. Volume I. 3rd ed. CRC Press, Inc. Boca Raton ,FL. 1994.,p. V4 3838]**PEER REVIEWED**

Vapor Density:

3.4 (AIR= 1)
[Patty, F. (ed.). Industrial Hygiene and Toxicology: Volume II: Toxicology. 2nd ed. New York: Interscience Publishers, 1963. 1981]**PEER REVIEWED**

Vapor Pressure:

0.6 mm Hg at 30 deg C
[Heisler SL, Friedlander SK; Atmos Environ 11: 157-168 (1977)]**PEER REVIEWED**

Other Chemical/Physical Properties:

CONVERSION FACTORS: 1 MG/L= 245 PPM; 1 PPM= 4.1 MG/CU M
[Patty, F. (ed.). Industrial Hygiene and Toxicology: Volume II: Toxicology. 2nd ed. New York: Interscience Publishers, 1963. 1981]**PEER REVIEWED**

Hydroxyl radical reaction rate constant = 2.38X10-11 cu cm/molecule-sec @ 25 deg C
[Atkinson R; J Phys Chem Ref Data Monograph 1 p. 137 (1989)]**PEER REVIEWED**

Polymerizes in water to a glassy form which regenerates the dialdehyde on vacuum distillation.
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 761]**PEER REVIEWED**

VP = 17 mm Hg @ 20 deg C; FP = -7 deg C /25% aqueous solution/; FP = -14 deg C /50% aqueous solution/
[Flick, E.W. (ed.). Industrial Solvents Handbook 4 th ed. Noyes Data Corporation., Park Ridge, NJ., 1991. 511]**PEER REVIEWED**

VP = 17 mm Hg @ 20 deg C; FP = -7 deg C /25% aqueous solution/
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 761]**PEER REVIEWED**

Chemical Safety & Handling:

Skin, Eye and Respiratory Irritations:

A severe skin and eye irritant in humans.
[Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 1734]**PEER REVIEWED**

Contact with liquid causes severe irritation of eyes and irritation of skin.
[U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.]**PEER REVIEWED**

Eye and respiratory irritation are noted at a level of 0.3 ppm.
[Ellenhorn, M.J., S. Schonwald, G. Ordog, J. Wasserberger. Ellenhorn's Medical Toxicology: Diagnosis and Treatment of Human Poisoning. 2nd ed. Baltimore, MD: Williams and Wilkins, 1997. 1219]**PEER REVIEWED**

Hazardous Reactivities & Incompatibilities:

Strong oxidizers, strong bases [Note: Alkaline solutions of glutaraldehyde (i.e., activated glutaraldehyde) react with alcohol, ketones, amines, hydrazines & proteins].
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 152]**PEER REVIEWED**

Hazardous Decomposition:

When heated to decomposition it emits acrid smoke and irritating fumes.
[Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996. 1734]**PEER REVIEWED**

Protective Equipment & Clothing:

Goggles or face shield; rubber gloves.
[U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.]**PEER REVIEWED**

Neoprene or butyl rubber gloves are protective. Latex rubber gloves are not as protective.
[Sullivan, J.B. Jr., G.R. Krieger (eds.). Hazardous Materials Toxicology-Clinical Principles of Environmental Health. Baltimore, MD: Williams and Wilkins, 1992. 983]**PEER REVIEWED**

Wear appropriate personal protective clothing to prevent skin contact.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 153]**PEER REVIEWED**

Wear appropriate eye protection to prevent eye contact.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 153]**PEER REVIEWED**

Eyewash fountains should be provided in areas where there is any possbility that workers could be exposed to the substance; this is irrespective of the recommendation involving the wearing of eye protection.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 153]**PEER REVIEWED**

Facilities for quickly drenching the body should be provided within the immediate work area for emergency use where there is a possibility of exposure. [Note: It is intended that these facilities provide a sufficient quantity or flow of water to quickly remove the substance from any body areas likely to be exposed. The actual determination of what constitutes an adequate quick drench facility depends on the specific circumstances. In certain instances, a deluge shower should be readily available, whereas in others, the availability of water from a sink or hose could be considered adequate.]
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No.

97-140. Washington, D.C. U.S. Government Printing Office, 1997. 153]**PEER REVIEWED**

Preventive Measures:

SRP: The scientific literature for the use of contact lenses in industry is conflicting. The benefit or detrimental effects of wearing contact lenses depend not only upon the substance, but also on factors including the form of the substance, characteristics and duration of the exposure, the uses of other eye protection equipment, and the hygiene of the lenses. However, there may be individual substances whose irritating or corrosive properties are such that the wearing of contact lenses would be harmful to the eye. In those specific cases, contact lenses should not be worn. In any event, the usual eye protection equipment should be worn even when contact lenses are in place.
PEER REVIEWED

Containment of vapors and prevention of skin contact are important industrial hygiene principles to help avoid sensitization of the skin and respiratory irritation and/or asthma. Proper skin protection must be provided as well as ventilation controls.
[Sullivan, J.B. Jr., G.R. Krieger (eds.). Hazardous Materials Toxicology-Clinical Principles of Environmental Health. Baltimore, MD: Williams and Wilkins, 1992. 983]**PEER REVIEWED**

The worker should immediately wash the skin when it becomes contaminated.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 153]**PEER REVIEWED**

Work clothing that becomes wet or significantly contaminated should be removed and replaced.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 153]**PEER REVIEWED**

Contact lenses should not be worn when working with this chemical.
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 153]**PEER REVIEWED**

SRP: Contaminated protective clothing should be segregated in such a manner so that there is no direct personal contact by personnel who handle, dispose, or clean the clothing. Quality assurance to ascertain the completeness of the cleaning procedures should be implemented before the decontaminated protective clothing is returned for reuse by the workers. Contaminated clothing should not be taken home at end of shift, but should remain at employee's place of work for cleaning.
PEER REVIEWED

Stability/Shelf Life:

ACID GLUTARALDEHYDE IS MORE STABLE THAN ALKALINE GLUTARALDEHYDE

[Osol, A. and J.E. Hoover, et al. (eds.). Remington's Pharmaceutical Sciences. 15th ed. Easton, Pennsylvania: Mack Publishing Co., 1975. 1103]**PEER REVIEWED**

STABLE IN LIGHT, OXIDIZES IN AIR, POLYMERIZES IN HEAT
[Osol, A. and J.E. Hoover, et al. (eds.). Remington's Pharmaceutical Sciences. 15th ed. Easton, Pennsylvania: Mack Publishing Co., 1975. 1103]**PEER REVIEWED**

ALKALINE SOLUTION DEPOSITS POLYMERIC FILM AFTER FEW HR
[Goodman, L.S., and A. Gilman. (eds.) The Pharmacological Basis of Therapeutics. 5th ed. New York: Macmillan Publishing Co., Inc., 1975. 994]**PEER REVIEWED**

GLUTARAL LOSES ACTIVITY WITHIN 2 WK AFTER PREPN
[American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994. 1620]**PEER REVIEWED**

Disposal Methods:

SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices.
PEER REVIEWED

Occupational Exposure Standards:

Threshold Limit Values:

Ceiling Limit: 0.05 ppm, sensitizer. /Activated and inactivated/
[American Conference of Governmental Industrial Hygienists. TLVs & BEIs: Threshold limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices for 2002. Cincinnati, OH. 2002.34]**QC REVIEWED**

A4; Not classifiable as a human carcinogen.
[American Conference of Governmental Industrial Hygienists. TLVs & BEIs: Threshold limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices for 2002. Cincinnati, OH. 2002.34]**QC REVIEWED**

NIOSH Recommendations:

Recommended Exposure Limit: Ceiling value: 0.2 ppm (0.8 mg/cu m).
[NIOSH. NIOSH Pocket Guide to Chemical Hazards. DHHS (NIOSH) Publication No. 97-140. Washington, D.C. U.S. Government Printing Office, 1997. 152]**PEER REVIEWED**

Manufacturing/Use Information:

Major Uses:

For Glutaraldehyde (USEPA/OPP Pesticide Code: 043901) ACTIVE products with label matches. /SRP: Registered for use in the U.S. but approved pesticide uses may change periodically and so federal, state and local authorities must be consulted for currently approved uses./
[U.S. Environmental Protection Agency/Office of Pesticide Program's Chemical Ingredients Database on Glutaraldehyde (111-30-8). Available from the Database Query page at http://www.cdpr.ca.gov/docs/epa/epamenu.htm as of May 24, 2001.]**PEER REVIEWED**

EMBALMING FLUID
[Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. Clinical Toxicology of Commercial Products. 4th ed. Baltimore: Williams and Wilkins, 1976.,p. II-123]**PEER REVIEWED**

Intermediate; cross-linking protein and polyhydroxy materials; tanning of soft leathers
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 13th ed. New York, NY: John Wiley & Sons, Inc. 1997. 542]**PEER REVIEWED**

CHEM INT FOR ADHESIVES, SEALANTS, ELECTRICAL PRODUCTS
[SRI]**PEER REVIEWED**

In sterilization of endoscopic instruments thermometers, rubber or plastic equipment which cannot be heat sterilized
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 761]**PEER REVIEWED**

Used as a biocide in the oil industry
[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. VA16 (1990) 567]**PEER REVIEWED**

The most popular enzyme cross-linking reagent; microbiol cells are also cross-linked with glutaraldehyde to yield cell pellets
[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. VA9 (1987) 386]**PEER REVIEWED**

Skin disinfectant
[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. VA8 (1987) 555]**PEER REVIEWED**

DISINFECTANT THAT IS VERY GOOD NOT ONLY AGAINST VEGETATIVE BACTERIA BUT ALSO AGAINST SPORES. ITS EFFICACY AGAINST FUNGI & VIRUSES IS GOOD. ...DISINFECTANT OF CHOICE FOR COLD STERILIZATION OF SURGICAL INSTRUMENTS BUT IS BEING DISPLACED BY ETHYLENE OXIDE... GLUTARALDEHYDE AEROSOLS ARE ALSO USED TO "STERILIZE" HOSPITAL ROOMS; OPERATING AREAS, ETC. ACID GLUTARALDEHYDE IS MORE EFFECTIVE THAN ALKALINE GLUTARALDEHYDE...

[Osol, A. and J.E. Hoover, et al. (eds.). Remington's Pharmaceutical Sciences. 15th ed. Easton, Pennsylvania: Mack Publishing Co., 1975. 1103]**PEER REVIEWED**

Disinfectant
[Farm Chemicals Handbook 2001. Willoughby, Ohio: Meister 2001.,p. C 210]**PEER REVIEWED**

Gelatine hardening agent; biocide (cosmetics, water treatment, oilfield applications); leather tannive auxiliary
[Ashford, R.D. Ashford's Dictionary of Industrial Chemicals. London, England: Wavelength Publications Ltd., 1994. 450]**PEER REVIEWED**

MEDICATION
PEER REVIEWED

TISSUE FIXATION
PEER REVIEWED

Manufacturers:

Polysciences, Inc., 400 Valley Rd., Warrington, PA 18976, (800) 523-2575; Production site: Warrington, PA 18976
[SRI International. 2000 Directory of Chemical Producers -- United States. SRI Consulting, Menlo Park: CA 2000 654]**PEER REVIEWED**

Union Carbide Corp., 39 Old Ridgebury Rd., Danbury, CT 06817-001, (203) 794-2000; Production site: Institute, WV 25103
[SRI International. 2000 Directory of Chemical Producers -- United States. SRI Consulting, Menlo Park: CA 2000 654]**PEER REVIEWED**

Vinings Industries, Inc., 245 TownPark Drive, Suite 200, Kennesaw, GA 30144, (800) 347-1542; Production site: Marietta, GA 30060
[SRI International. 2000 Directory of Chemical Producers -- United States. SRI Consulting, Menlo Park: CA 2000 654]**PEER REVIEWED**

Methods of Manufacturing:

THE 1:1 DIELS-ALDER ADDUCT OF ACROLEIN & VINYL ALKYL ETHER IS HYDROLYZED YIELDING GLUTARALDEHYDE & ALKANOL.
[Osol, A. and J.E. Hoover, et al. (eds.). Remington's Pharmaceutical Sciences. 15th ed. Easton, Pennsylvania: Mack Publishing Co., 1975. 1102]**PEER REVIEWED**

Prepared by heating 2-ethoxy-3,4-dihydro-2H-pyran with aq HCl
[Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996. 761]**PEER REVIEWED**

General Manufacturing Information:

COST & LACK OF STABILITY ARE IMPORTANT DRAWBACKS TO ITS USE.
[American Medical Association, AMA Department of Drugs, AMA Drug Evaluations. 3rd ed. Littleton, Massachusetts: PSG Publishing Co., Inc., 1977. 894]**PEER REVIEWED**

NEITHER ALKALINE NOR ACIDIC SOLN IS DAMAGING TO MOST SURGICAL INSTRUMENTS. ALKALINE DEPOSITS POLYMERIC FILM AFTER FEW HR.
[Goodman, L.S., and A. Gilman. (eds.) The Pharmacological Basis of Therapeutics. 5th ed. New York: Macmillan Publishing Co., Inc., 1975. 994]**PEER REVIEWED**

...SUPERIOR TO FORMALDEHYDE AS STERILIZING AGENT. ... /AS 2% ALKALINE SOLN IN 70% ISOPROPANOL/...PERIOD OF 10 HR IS NECESSARY TO STERILIZE DRIED SPORES. ...ACIDIC /GLUTARALDEHYDE/ SOLN KILLS DRIED SPORES IN 20 MIN...
[Goodman, L.S., and A. Gilman. (eds.) The Pharmacological Basis of Therapeutics. 5th ed. New York: Macmillan Publishing Co., Inc., 1975. 944]**PEER REVIEWED**

Formulations/Preparations:

USEPA/OPP Pesticide Code 043901; Trade Names: Cidex, component of; Odix, component of; Aldesan; Alhydex; Glutaralum; Hospex; NCI-C55425; Sonacide; Coldcide-25 Microbiocide Concentrate; GKN-O Microbiocide Concentrate (043901+069104+069154).
[U.S. Environmental Protection Agency/Office of Pesticide Program's Chemical Ingredients Database on Glutaraldehyde (111-30-8). Available from the Database Query page at http://www.cdpr.ca.gov/docs/epa/epamenu.htm as of May 24, 2001.]**PEER REVIEWED**

IT HAS BEEN MARKETED AS 2% ALKALINE SOLN IN 70% ISOPROPANOL...
[Goodman, L.S., and A. Gilman. (eds.) The Pharmacological Basis of Therapeutics. 5th ed. New York: Macmillan Publishing Co., Inc., 1975. 994]**PEER REVIEWED**

CIDEX (ARBROOK) TOPICAL: SOLN (AQ) 2%.
[American Medical Association, AMA Department of Drugs, AMA Drug Evaluations. 3rd ed. Littleton, Massachusetts: PSG Publishing Co., Inc., 1977. 894]**PEER REVIEWED**

Grades: 99%; 50% biological soln; 25% soln.
[Lewis, R.J., Sr (Ed.). Hawley's Condensed Chemical Dictionary. 13th ed. New York, NY: John Wiley & Sons, Inc. 1997. 541]**PEER REVIEWED**

EMPLOYED AS 25% SOLN IN WATER FOR EMBALMING FLUID.
[Gosselin, R.E., H.C. Hodge, R.P. Smith, and M.N. Gleason. Clinical Toxicology of Commercial Products. 4th ed. Baltimore: Williams and Wilkins, 1976.,p. II-125]**PEER REVIEWED**

2% AQ SOLN BUFFERED WITH 0.3% SODIUM CARBONATE TO PH OF 7.5-8.5 IS USEFUL FOR DISINFECTION AND STERILIZATION OF ENDOSCOPIC INSTRUMENTS & PLASTIC & RUBBER APPARATUS USED FOR INHALATION THERAPY &

ANESTHESIA.
[American Medical Association, AMA Department of Drugs, AMA Drug Evaluations. 3rd ed. Littleton, Massachusetts: PSG Publishing Co., Inc., 1977. 894]**PEER REVIEWED**

Electron microscopy grade is highly purified
[Kuney, J.H., J.M. Mullican (eds.). Chemcyclopedia. Washington, DC: American Chemical Society, 1994. 82]**PEER REVIEWED**

Biocide; supplied in acid solution and subsequently buffered to pH 8
[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. VA16 (1990) 567]**PEER REVIEWED**

U. S. Production:

(1974) PROBABLY GREATER THAN 4.54X10+5 GRAMS
[SRI]**PEER REVIEWED**

(1976) PROBABLY GREATER THAN 2.27X10+6 GRAMS
[SRI]**PEER REVIEWED**

Laboratory Methods:

Analytic Laboratory Methods:

OSHA Method No. 64 Glutaraldehyde Issue June 1987. HPLC/UV Reliable quantitation limit = 18 ug/cu m.
[OSHA; Analytical Methods Manual. 2nd ed., Part 1 Organic Substances, Vol I Meth 1-28, Vol II, meth 29-54, Vol III Meth 55-80. Jan 1990. Vol IV Meth 81-102, Apr 1993. US Dept Labor Occupational Safety and Health, Admin, Direct Tech Supp, OSHA Technical Center, Salt Lake City, Utah]**PEER REVIEWED**

NIOSH Method 2531. Determination of Glutaraldehyde by High Performance Liquid Chromatography with UV Detection. This method is applicable to air samples. Detection limit = 0.01 mg/cu m.
[U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health. NIOSH Manual of Analytical Methods. 4th ed. Methods A-Z & Supplements. Washington, DC: U.S. Government Printing Office, Aug 1994.]**PEER REVIEWED**

Special References:

Special Reports:

DHHS/NTP; NTP Technical Report on Toxicity Studies of Glutaraldehyde Administered by Inhalation to F344/N Rats and B6C3F1 Mice. Toxicity Rpt Series No. 25 NIH Publication No. 93-3348 (1993)

Synonyms and Identifiers:

Synonyms:

ALDESEN
PEER REVIEWED

CIDEX
PEER REVIEWED

1,3-Diformylpropane
PEER REVIEWED

Pesticide Code: 043901
PEER REVIEWED

GLUTARAL
PEER REVIEWED

GLUTARALDEHYD (CZECH)
PEER REVIEWED

GLUTARDIALDEHYDE
PEER REVIEWED

GLUTARIC ACID DIALDEHYDE
PEER REVIEWED

GLUTARIC ALDEHYDE
PEER REVIEWED

GLUTARIC DIALDEHYDE
PEER REVIEWED

HOSPEX
PEER REVIEWED

NCI-C55425
PEER REVIEWED

PENTANEDIAL
PEER REVIEWED

1,5-PENTANEDIAL
PEER REVIEWED

1,5-PENTANEDIONE
PEER REVIEWED

SONACIDE
PEER REVIEWED

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[U.S. Environmental Protection Agency/Office of Pesticide Program's Chemical Ingredients Database on Glutaraldehyde (111-30-8). Available from the Database Query page at http://www.cdpr.ca.gov/docs/epa/epamenu.htm as of May 24, 2001.]**PEER REVIEWED**

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[American Medical Association, AMA Department of Drugs, AMA Drug Evaluations. 3rd ed. Littleton, Massachusetts: PSG Publishing Co., Inc., 1977. 894]**PEER REVIEWED**

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Biocide; supplied in acid solution and subsequently buffered to pH 8
[Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present.,p. VA16 (1990) 567]**PEER REVIEWED**

Hazardous Substances Databank Number: 949

NIOSH Safety and Health Topic:

Glutaraldehyde

Overview

Glutaraldehyde is a colorless, oily, liquid-chemical with a pungent odor. It is used for a number of applications such as the following:

- A cold sterilant in the health care industry
- A cross-linking and tanning agent
- A biocide in metalworking fluids and in oil and gas pipelines
- An antimicrobial in water-treatment systems
- A slimicide in paper manufacturing
- A preservative in cosmetics
- A disinfectant in animal housing
- A tissue fixative in histology and pathology labs
- A hardening agent in the development of X-rays
- In embalming solutions
- In the preparation of grafts and bioprostheses
- In various clinical applications

In the health care industry, glutaraldehyde is most often used to disinfect equipment that cannot be heat sterilized such as dialysis instruments, surgical instruments, suction bottles, bronchoscopes, endoscopes, and ear, nose, and throat instruments.

The chemical is most often used in a diluted form with solutions ranging from 0.1% to 50% glutaraldehyde in water. Trade names for glutaraldehyde-containing formulations include Cidex®, Sonacide®, Sporicidin®, Hospex®, Omnicide®, Metricide®, Rapicide® and Wavicide®.

Workers can be exposed to glutaraldehyde through inhalation or skin contact. Health effects that may occur as a result of exposure to glutaraldehyde include but are not limited to the following:

- Throat and lung irritation
- Asthma and difficulty breathing
- Contact and/or allergic dermatitis
- Nasal irritation
- Sneezing
- Wheezing
- Burning eyes and conjunctivitis

Glutaraldehyde

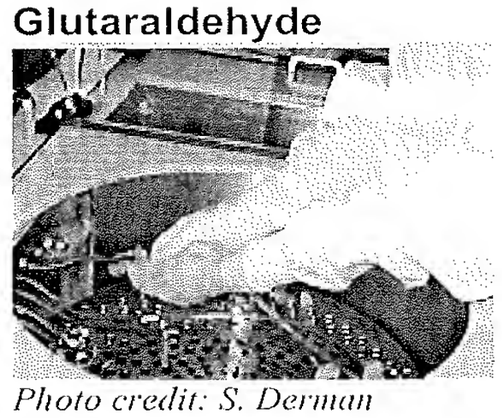

Photo credit: S. Derman

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Additional Resources

Related NIOSH Topic Pages

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The free Acrobat Reader is needed to open some of the files on this page.

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NIOSH Resources

NIOSH Glutaraldehyde: Occupational Hazards in Hospitals
DHHS (NIOSH) Publication No. 2001-115
Provides information about the adverse health effects of glutaraldehyde, describes how hospital workers can be exposed to glutaraldehyde, and identifies control methods and work practices to prevent or reduce exposure.
En Español

NIOSH Pocket Guide to Chemical Hazards
DHHS (NIOSH) Publication No. 2005-149
Key data provided for each chemical/substance includes name, structure/formula, CAS/RTECS Numbers, DOT ID, conversion factors, exposure limits, IDLH, chemical and physical properties, measurement methods, personal protection, respirator recommendations, symptoms, and first aid.

- Glutaraldehyde (CAS No. 111-30-8)

International Chemical Safety Cards (ICSC)
Essential health and safety information about chemicals for their use at the "shop floor" level by workers and employers in factories, agriculture, construction, and other work places.

- Glutaraldehyde (1,5-Pentanedial, Glutaric dialdehyde, Glutaral)
- Glutaraldehyde (50% solution), (1,5-Pentanedial 50% solution)

NIOSH Manual of Analytical Methods (NMAM)
Collection of methods for sampling and analysis of contaminants in workplace air and in the blood and urine of workers who are occupationally exposed.

- Glutaraldehyde (No. 2532) PDF only 25 kb (4 pages)
- Aldehydes, screening (No. 2539) PDF only 255 kb (10 pages)

NIOSH Current Intelligence Bulletin 55: Carcinogenicity of Acetaldehyde and Malonaldehyde, and Mutagenicity of Related Low-Molecular-Weight Aldehydes
DHHS (NIOSH) Publication No. 91-112
Information about the potential carcinogenicity and mutagenicity of acetaldehyde and malonaldehyde, the chemical reactivity and mutagenicity of nine related aldehydes, and includes guidelines for minimizing occupational exposures.

NIOSH Registry of Toxic Effects of Chemical Substances (RTECS): Glutaraldehyde
Includes detailed information about toxic health effects and official exposure recommendations and standards for glutaraldehyde.

Selected Journal and Abstract Citations

The following are selected journal articles about glutaraldehyde with NIOSH co-authors:

Vo E, Zhuang Z. [2009]. The use of aldehyde indicators to determine glutaraldehyde and alkaline glutaraldehyde contamination in chemical protective gloves. *Arch Environ Contam Toxicol* Jul; 57(1): 185-192.

Dankovic DA, Bailer A. [2007]. A glutaraldehyde risk assessment using benchmark doses: decisions, decisions, decisions! *Toxicologist*, Mar; 96(1): 336.

Vo E, Murray DK, Scott TL, Attar AJ. [2007]. Development of a novel colorimetric indicator pad for detecting aldehydes. *Talanta*, 2007 Aug; 73(1): 87-94.

Azadi S, Butterworth LF, Meade BJ. [2004]. Divergent immunological responses following glutaraldehyde exposure. *Toxicol Appl Pharmacol*, May; 197(1): 1-8.

Vo E. [2002]. Development of colorimetric indicators: a new technique to determine glutaraldehyde and alkaline glutaraldehyde contamination. *Proceedings of the International Conference on Occupational and Environmental Exposures of Skin to Chemicals: Science & Policy*, Arlington, VA, September 8-11. Morgantown, WV: National Institute for Occupational Safety and Health. Sep; 5.

NIOSH Health Hazard Evaluations

HHE Report No. HETA-2003-0205-3032, Interfaith Medical Center, Brooklyn, New York

HHE Report No. HETA-90-296-2149, Monongalia General Hospital, Morgantown, West Virginia

HHE Report No. HETA-86-226-1769, Montgomery Hospital, Norristown, Pennsylvania

HHE Report No. HETA-85-257-1791, Mercy Medical Center, Denver, Colorado

HHE Report No. HETA-84-535-1690, National Jewish Hospital, Denver, Colorado

NIOSHTIC-2

NIOSHTIC-2 is a searchable bibliographic database of occupational safety and health publications, documents, grant reports, and journal articles supported by NIOSH.

NIOSHTIC-2 search results on Glutaraldehyde

Other U.S. Government Resources

Occupational Safety and Health Administration (OSHA) Best Practices for the Safe Use of Glutaraldehyde in Health Care
Information to be used by health care employers and employees to understand and control exposures.
External Link: http://www.osha.gov/Publications/glutaraldehyde.pdf

OSHA Hospital eTool: Glutaraldehyde
Identifies possible employee exposure to glutaraldehyde in the workplace and provides possible solutions.
External Link: http://www.osha.gov/SLTC/etools/hospital/hazards/glutaraldehyde/glut.html

EPA: Reducing Ethylene Oxide and Glutaraldehyde Use
External Link: http://www.epa.gov/region09/waste/p2/projects/hospital/glutareth.pdf
PDF only (4 pages)

U.S. Food and Drug Administration (FDA) Device Evaluation Information: FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices
This chart provides information about several manufactured sterilants and high-level disinfectants including chemical trade names, active ingredients, sterilant contact conditions, and high level disinfectant contact conditions as recommended by the FDA.
External Link: http://www.fda.gov/cdrh/ode/germlab.html

Additional Resources

American Federation of Government Employees: Glutaraldehyde Information
External Link: http://www.afge.org/Index.cfm?Page=Glutaraldehyde

California Department of Public Health: Glutaraldehyde Fact Sheet
External Link: http://www.cdph.ca.gov/programs/hesis/Documents/glutaral.pdf
PDF only 55KB (5 pages)

Dow Biocides: Glutaraldehyde Safety & Handling - Hospital Disinfection and Hazards
Available in English, German, Spanish, Portuguese, Chinese and Japanese.
External Link: http://www.dow.com/biocides/glut/literature.htm

New Jersey Hazardous Substance Fact Sheets: Glutaraldehyde
External Link: http://nj.gov/health/eoh/rtkweb/documents/fs/0960.pdf
PDF only 71KB (6 pages)

New Jersey: Guidelines for Safe Use of Glutaraldehyde in Health Care Facilities
External Link: http://www.nj.gov/health/eoh/survweb/glutar.pdf
PDF only 77KB (9 pages)

New Zealand: The Safe Occupational Use of Glutaraldehyde in the Health Industries
External Link: http://www.osh.dol.govt.nz/order/catalogue/pdf/glutaral.pdf
PDF only 83KB (22 pages)

Organization for Economic Cooperation and Development (OECD) Screening Information Data Sets (SIDS): Glutaraldehyde
External Link: http://www.inchem.org/documents/sids/sids/111308.pdf
PDF only (83 pages)

United Kingdom Health and Safety Executive Research Report (RR445): An Evaluation of Chemical Disinfecting Agents Used in Endoscopy Suites in the National Health Service
External Link: http://www.hse.gov.uk/research/rrhtm/rr445.htm

Sustainable Hospitals (Lowell Center for Sustainable Production) Glutaraldehyde Case Studies and Fact Sheets
External Link: http://www.sustainablehospitals.org/cgi-bin/DB_Index.cgi

Related NIOSH Safety and Health Topics

Chemical Safety

Control Banding

Eye Safety

Formaldehyde

Health Care Workers

Protective Clothing

Skin Exposure and Effects

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National Institute for Occupational Safety and Health NIOSH

RTECS

Glutaraldehyde

RTECS #: MA2450000

CAS #: 111-30-8

UPDATE: May 2009	MW: 100.13	MF: $C_5H_8O_2$

NOTE:

- TOXICITY DATA HAVE NOT BEEN EVALUATED. OMISSION OF A SUBSTANCE OR NOTATION DOES NOT IMPLY ANY RELIEF FROM REGULATORY RESPONSIBILITY.

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SYNONYMS:

1. 1,3 - Diformylpropane
2. 1,5 - Pentanedial
3. 1,5 - Pentanedione
4. Aldehyd glutarowy (Polish)
5. Cidex
6. Glutaraldehyd (Czech)
7. Glutaral
8. Glutaraldehyde (ACGIH)
9. Glutardialdehyde
10. Glutaric dialdehyde
11. NCI - C55425
12. Potentiated acid glutaraldehyde
13. Sonacide

SKIN AND EYE IRRITATION DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
eye rabbit	1 mg	severe	UCDS** 1/30/1970
eye rabbit	250 µg/24 hour	severe	85JCAE -,272,1986
eye woman	200 ppb	severe	TOXID9 72,292,2003
skin human	6 mg/3 day- intermittent	severe	85DKA8 -,127,1977
skin rabbit	13 mg open irritation test	mild	UCDS** 1/30/1970
skin rabbit	2 mg/24 hour	severe	85JCAE -,272,1986

MUTATION DATA AND REFERENCES:

SYSTEM TEST	ROUTE/ ORGANISM/ TISSUE	DOSE	REFERENCE
cytogenetic analysis	hamster ovary	160 µg/L	ENMUDM 7,1,1985
DNA damage	chicken leukocyte	8 pph	CELLB5 5,45,1975
DNA damage	hamster fibroblast	2,500 ppm	SFCRAO 23,346,1970
DNA damage	hamster fibroblast	20 µmol/L/1 hour	MUREAV 649,146,2008
DNA damage	human lymphocyte	10 µmol/L	EMMUEG 17(Suppl 19),71,1991

DNA damage	human leukocyte	5 µmol/L	MUREAV 468,93,2000
DNA damage	mammal (species unspecified) lymphocyte	2,500 µmol/L	MUREAV 283,131,1992
DNA repair	Bacillus subtilis	1 mg/L	MUREAV 193,21,1988
mutation in microorganisms	Escherichia coli	62,500 ng/plate (-enzymatic activation step)	MUREAV 412,17,1998
mutation in microorganisms	Salmonella typhimurium	500 nmol/L (+enzymatic activation step)	MUREAV 148,25,1985
mutation in microorganisms	Salmonella typhimurium	150 µg/plate (-enzymatic activation step)	ENMUDM 5(Suppl 1),3,1983
mutation in microorganisms	Salmonella typhimurium	0.5 mg/plate/48 hour (+enzymatic activation step)	JAPTO* 22,45,2001
mutation in microorganisms	Salmonella typhimurium	0.25 mg/plate/3 day (-enzymatic activation step)	MUREAV 521,19,2002
mutation in microorganisms	Salmonella typhimurium	25 µg/plate/72 hour (-enzymatic activation step)	MUTAEX 15,495,2000
micronucleus test	hamster fibroblast	10 µmol/L/1 hour	MUREAV 649,146,2008
mutation in mammalian somatic cells	mouse lymphocyte	8 mg/L	EMMUEG 11,91,1988
other mutation test systems	non-mammalian species other cell types	50 mmol/L	ECREAL 95,233,1975
sister chromatid exchange	hamster ovary	110 µg/L	ENMUDM 7,1,1985
sister chromatid exchange	hamster fibroblast	10 µmol/L/1 hour	MUREAV 649,146,2008

REPRODUCTIVE EFFECTS DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE

oral mouse	lowest published toxic dose: 50 gm/kg (6-15 day pregnant)	Reproductive: Specific developmental abnormalities: Central nervous system Reproductive: Specific developmental abnormalities: Craniofacial (including nose and tongue) Reproductive: Specific developmental abnormalities: Musculoskeletal system	TJADAB 22,51,1980
oral mouse	lowest published toxic dose: 8 gm/kg (6-15 day pregnant)	Reproductive: Effects on embryo or fetus: Fetotoxicity (except death, e.g., stunted fetus)	TJADAB 22,51,1980
oral rat	lowest published toxic dose: 875 mg/kg (35 day male)	Reproductive: Paternal effects: Testes, epididymis, sperm duct Reproductive: Paternal effects: Prostate, seminal vesicle, Cowper's gland, accessory glands	OYYAA2 12,11,1976
oral rat	lowest published toxic dose: 4,370 mg/kg (35 day prior to copulation)	Reproductive: Maternal effects: Uterus, cervix, vagina	OYYAA2 12,11,1976
oral rat	lowest published toxic dose: 1 gm/kg (6-15 day pregnant)	Reproductive: Effects on embryo or fetus: Fetotoxicity (except death, e.g., stunted fetus)	TOLED5 63,147,1992
oral rat	lowest published toxic dose: 5.3 gm/kg (84 day male/70 day prior to copulation-4 week after birth)	Reproductive: Effects on newborn: Growth statistics (e.g., reduced weight gain) Reproductive: Effects on newborn: Other postnatal measures or effects Reproductive: Effects on newborn: Delayed effects	JTEHD6 61,107,2000
oral rat	lowest published toxic dose: 167.4 mg/kg (multigenerations)	Reproductive: Effects on newborn: Growth statistics (e.g., reduced weight gain) Reproductive: Effects on newborn: Delayed effects	JTEHD6 61,107,2000

oral rabbit	lowest published toxic dose: 585 mg/kg (7-19 day pregnant)	Reproductive: Other effects on female Reproductive: Effects on fertility: Post- implantation mortality (e.g., dead and/or resorbed implants per total number of implants) Reproductive: Effects on embryo or fetus: Fetotoxicity (except death, e.g., stunted fetus)	NTIS** OTS0526410

TUMORIGENIC DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
oral rat	lowest published toxic dose: 2,912 mg/kg/104 week-continuous	Tumorigenic: Carcinogenic by RTECS criteria Blood: Leukemia Tumorigenic: Increased incidence of tumors in susceptible strains	TXCYAC 175,177,2002
oral rat	lowest published toxic dose: 2,912 mg/kg/104 week-intermittent	Tumorigenic: Carcinogenic by RTECS criteria Blood: Leukemia Tumorigenic: Increased incidence of tumors in susceptible strains	TXCYAC 175,177,2002

ACUTE TOXICITY DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
inhalation rat	lethal concentration (50 percent kill): 480 mg/m^3/4 hour	N/R	EPASR* 8EHQ-1290-1008

inhalation rabbit	lowest published toxic concentration: 500 ppm	Eye: Conjunctiva irritation Lung, Thorax, or Respiration: Cough	VCVGK* -,404,1984
inhalation woman	lowest published toxic concentration: 200 ppb	Olfaction: Other olfaction effects	TOXID9 72,292,2003
intraperitoneal mouse	lethal dose (50 percent kill): 13,900 µg/kg	N/R	IYKEDH 10,232,1979
intraperitoneal rat	lethal dose (50 percent kill): 17,900 µg/kg	N/R	IYKEDH 10,232,1979
intravenous mouse	lethal dose (50 percent kill): 15,400 µg/kg	N/R	OYYAA2 19,503,1980
intravenous rat	lethal dose (50 percent kill): 9,800 µg/kg	N/R	EPASR* 8EHQ-1290-1008
oral duck	lethal dose (50 percent kill): 820 mg/kg	Behavioral: Somnolence (general depressed activity) Behavioral: Food intake (animal)	NTIS** OTS0526410-1
oral guinea pig	lethal dose (50 percent kill): 50 mg/kg	Behavioral: Altered sleep time (including change in righting reflex) Behavioral: Somnolence (general depressed activity) Behavioral: Excitement	GISAAA 52 (3),77,1987
oral mouse	lethal dose (50 percent kill): 100 mg/kg	N/R	OYYAA2 19,503,1980
oral mouse	lethal dose (50 percent kill): 231 mg/kg	Lung, Thorax, or Respiration: Other changes Liver: Other changes Kidney, Ureter, and Bladder: Other changes	VCVGK* -,404,1984
oral rat	lethal dose (50 percent kill): 134 mg/kg	N/R	OYYAA2 19,503,1980
oral rat	lethal dose (50 percent kill): 140 mg/kg	Lung, Thorax, or Respiration: Other changes Liver: Other changes Kidney, Ureter, and Bladder: Other changes	VCVGK* -,404,1984

subcutaneous mouse	lethal dose (50 percent kill): >590 mg/kg	N/R	NIIRDN - ,395,1995
subcutaneous rat	lethal dose (50 percent kill): >750 mg/kg	N/R	NIIRDN - ,395,1995
skin mouse	lethal dose (50 percent kill): >5,840 mg/kg	Skin: After systemic exposure: Dermatitis, other	OYYAA2 12,11,1976
skin mouse	lowest published toxic dose: 0.1 pph	Immunological Including Allergic: Hypersensitivity delayed (multiple organ involvement)	TOXID9 66,79,2002
skin rat	lethal dose (50 percent kill): >2,500 mg/kg	Skin: After systemic exposure: Dermatitis, other	OYYAA2 12,11,1976
skin rabbit	lethal dose (50 percent kill): 560 µL/kg	N/R	UCDS** 11/4/1971

OTHER MULTIPLE DOSE DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
inhalation mouse	lowest published toxic concentration: 16 ppm/6 hour/2 week- intermittent	Olfaction: Other olfaction effects Lung, Thorax, or Respiration: Other changes Related to Chronic Data: Death in the "MULTIPLE DOSE" data type field	NTPTR* NIH-93-3348
inhalation mouse	lowest published toxic concentration: 1,000 ppb/6 hour/13 week- intermittent	Olfaction: Other olfaction effects Nutritional and Gross Metabolic: Weight loss or decreased weight gain Related to Chronic Data: Death in the "MULTIPLE DOSE" data type field	NTPTR* NIH-93-3348
inhalation mouse	lowest published toxic concentration: 250 ppb/6 hour/2 year- intermittent	Olfaction: Other olfaction effects Nutritional and Gross Metabolic: Weight loss or decreased weight gain	TOXID9 48,341,1999
		Olfaction: Other olfaction effects Lung, Thorax, or Respiration:	

inhalation rat	lowest published toxic concentration: 5 ppm/6 hour/2 week- intermittent	Other changes Related to Chronic Data: Death in the "MULTIPLE DOSE" data type field	NTPTR* NIH-93-3348
inhalation rat	lowest published toxic concentration: 1,000 ppb/6 hour/13 week- intermittent	Olfaction: Other olfaction effects Nutritional and Gross Metabolic: Weight loss or decreased weight gain	NTPTR* NIH-93-3348
inhalation rat	lowest published toxic concentration: 500 ppb/6 hour/2 year- intermittent	Olfaction: Other olfaction effects Nutritional and Gross Metabolic: Weight loss or decreased weight gain Related to Chronic Data: Death in the "MULTIPLE DOSE" data type field	TOXID9 48,341,1999
oral rat	lowest published toxic dose: 12,376 mg/kg/2 year- continuous	Kidney, Ureter, and Bladder: Other changes in urine composition Kidney, Ureter, and Bladder: Changes in bladder weight Nutritional and Gross Metabolic: Weight loss or decreased weight gain	TOXID9 15,203,1995
oral rat	lowest published toxic dose: 54,600 µg/kg/26 week- intermittent	Liver: Fatty liver degeneration Nutritional and Gross Metabolic: Weight loss or decreased weight gain Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: True cholinesterase	GISAAA 52 (3),77,1987
oral rat	lowest published toxic dose: 11,410 mg/kg/7 day- intermittent	Nutritional and Gross Metabolic: Weight loss or decreased weight gain	NTIS** OTS0535072
oral rat	lowest published toxic dose: 122.5 mg/kg/1 week- continuous	Behavioral: Fluid intake	JTEHD6 61,107,2000
oral	lowest published toxic	Behavioral: Food intake	JTEHD6

rat	dose: 967 mg/kg/2 week- continuous	(animal)	61,107,2000
oral rat	lowest published toxic dose: 688.8 mg/kg/1 week- continuous	Behavioral: Food intake (animal)	JTEHD6 61,107,2000
oral rat	lowest published toxic dose: 117.5 mg/kg/235 day- intermittent	Endocrine: Changes in thymus weight Blood: Normocytic anemia Blood: Changes in other cell count (unspecified)	VCVGK* - ,404,1994
oral rat	lowest published toxic dose: 1,547 mg/kg/13 week- intermittent	Kidney, Ureter, and Bladder: Urine volume decreased or anuria Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: Multiple enzyme effects	TXCYAC 175,177,2002
oral rat	lowest published toxic dose: 9,282 mg/kg/78 week- intermittent	Kidney, Ureter, and Bladder: Urine volume decreased or anuria Kidney, Ureter, and Bladder: Changes in kidney weight Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: Multiple enzyme effects	TXCYAC 175,177,2002
subcutaneous rat	lowest published toxic dose: 175 mg/kg/35 day- continuous	Liver: Changes in liver weight Endocrine: Changes in spleen weight Blood: Normocytic anemia	OYYAA2 12,11,1976
skin human	lowest published toxic concentration: 1 pph/48 hour- continuous	Skin: After topical application: Dermatitis, allergic	AJCDE* 13,177,2002

REVIEWS:		
ORGANIZATION	**STANDARD**	**REFERENCE**

American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value	ceiling concentration 0.05 ppm (sen)	DTLVS* TLV/BEI,2007
American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value	Not classifiable as human carcinogen	DTLVS* TLV/BEI,2007
TOXICOLOGY REVIEW		DPIRDU 1 (7),2,1981
TOXICOLOGY REVIEW		CRTXB2 22,143,1992
TOXICOLOGY REVIEW		JACTDZ 15,98,1996
TOXICOLOGY REVIEW		MUREAV 543,201,2003
TOXICOLOGY REVIEW		EMMUEG 39,69,2002
TOXICOLOGY REVIEW		MUREAV 589,136,2005
TOXICOLOGY REVIEW		HPCQA4 38,527,2007
TOXICOLOGY REVIEW		HUTOX* - ,649,1996

STANDARDS AND REGULATIONS:

ORGANIZATION	STANDARD	REFERENCE
Environmental Protection Agency (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 1988	PESTICIDE SUBJECT TO REGISTRATION OR RE-REGISTRATION	FEREAC 54,7740,1989
Occupational Exposure Limit - AUSTRALIA	ceiling concentration 0.1 ppm (0.41 mg/m^3), JUL2008	
Occupational Exposure Limit - BELGIUM	short term exposure limit 0.05 ppm (0.21 mg/m^3), MAR2002	
Occupational Exposure Limit - DENMARK	ceiling concentration 0.2 ppm (0.8 mg/m^3), OCT 2002	
Occupational Exposure Limit - FINLAND	CEILING 0.1 ppm, JAN1999	
	VME 0.1 ppm (0.4 mg/m^3), VLE 0.2 ppm (0.8	

Occupational Exposure Limit - FRANCE	mg/m^3), FEB2006
Occupational Exposure Limit - GERMANY	MAK 0.21 mg/m^3 (0.05 mL/m^3) (airway and skin, sen), 2005
Occupational Exposure Limit - JAPAN	Occupational Exposure Limit- continuous 0.03 ppm, sen, APR2007
Occupational Exposure Limit - KOREA	ceiling concentration 0.2 ppm (0.7 mg/m^3), 2006
Occupational Exposure Limit - MEXICO	peak 0.2 ppm (0.7 mg/m^3), 2004
Occupational Exposure Limit - THE NETHERLANDS	MAC- continuous 0.25 mg/m^3, 2003
Occupational Exposure Limit - NEW ZEALAND	short term exposure limit 0.05 ppm, sen, JAN2002
Occupational Exposure Limit - NORWAY	time-weighted average 0.2 ppm (0.8 mg/m^3), JAN1999
Occupational Exposure Limit - RUSSIA	short term exposure limit 5 mg/m^3, JUN2003
Occupational Exposure Limit - SWEDEN	ceiling concentration 0.2 ppm (0.8 mg/m^3), Sen, JUN2005
Occupational Exposure Limit - SWITZERLAND	MAK- week 0.05 ppm (0.21 mg/m^3),KZG- week 0.1 ppm (0.42 mg/m^3), DEC2006
Occupational Exposure Limit - UNITED KINGDOM	time-weighted average 0.05 ppm; short term exposure limit 0.05 ppm (sen), 2005
Occupational Exposure Limit IN ARGENTINA, BULGARIA, COLOMBIA, JORDAN	American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value; Not classifiable as human carcinogen
Occupational Exposure Limit IN SINGAPORE, VIETNAM	American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value Not classifiable as human carcinogen

NIOSH DOCUMENTATION AND SURVEILLANCE:

ORGANIZATION	STANDARD or SURVEY	REFERENCE
National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Level TO GLUTARALDEHYDE-air	ceiling concentration 0.2 ppm	NIOSH* DHHS #92-100,1992
	National Occupational Hazard Survey 1974: Hazard Code: 84349;	

National Occupational Hazard Survey 1974	Number of Industries 11; Total Number of Facilities 2,069; Number of Occupations 25; Total Number of Employees Exposed 12,954
National Occupational Exposure Survey 1983	National Occupational Exposure Survey 1983: Hazard Code: 84349 EXIT ; Number of Industries 35; Total Number of Facilities 9,475; Number of Occupations 63; Total Number of Employees Exposed 367,330; Total Number of Female Employees Exposed 265,564

STATUS IN FEDERAL AGENCIES:	
ORGANIZATION	**REFERENCE**
EPA GENETOX PROGRAM 1988, Negative: CHO gene mutation	
EPA TSCA Section 8(b) CHEMICAL INVENTORY	
Used in leather tanning and in embalming fluids and as a germicide and crosslinking agent	
EPA TSCA Section 8(d) unpublished health/safety studies	
EPA TSCA TEST SUBMISSION (TSCATS) DATA BASE, JANUARY 2001	
NIOSH CURRENT INTELLIGENCE BULLETIN #55, September 1991	
NIOSH Analytical Method, 1994: Glutaraldehyde, 2532	
NCI Carcinogenesis Studies (inhal);no evidence:mouse,rat	
NTP Toxicity studies, RPT# TOX-25, October 2000	
OSHA ANALYTICAL METHOD #ID-64	

REFERENCES:	
CODEN	**REFERENCE**
85DKA8	"Cutaneous Toxicity, Proceedings of the 3rd Conference, 1976," Drill, V.A., and P. Lazar, eds., New York, Academic Press, Inc. 1977
85JCAE	"Prehled Prumyslove Toxikologie; Organicke Latky," Marhold, J., Prague, Czechoslovakia, Avicenum, 1986
AJCDE*	American Journal of Contact Dermatitis: Official Journal of the American Contact Dermatitis Society (Philadelphia, PA : W.B. Saunders, Harcourt Brace

	Jovanovich) V.1-14 1990-2003.
CELLB5	Cell (Cambridge, Mass.). (MIT Press, 28 Carleton St., Cambridge, MA 02142) V.1- 1974-
CRTXB2	CRC Critical Reviews in Toxicology. (CRC Press, Inc., 2000 Corporate Blvd., NW, Boca Raton, FL 33431) V.1- 1971-
DPIRDU	Dangerous Properties of Industrial Materials Report. (Van Nostrand Reinhold, 115 Fifth Ave., New York, NY 10003) V.1- 1981-
DTLVS*	The Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs) booklet issues by American Conference of Governmental Industrial Hygienists (ACGIH), Cincinnati, OH, 1996
ECREAL	Experimental Cell Research. (Academic Press, Inc., 1 E. First St., Duluth, MN 55802) V.10- 1950-
EMMUEG	Environmental and Molecular Mutagenesis. (Alan R. Liss, Inc., 41 E. 11th St., New York, NY 10003) V.10- 1987-
ENMUDM	Environmental Mutagenesis. (New York, NY) V.1-9, 1979-87. For publisher information, see EMMUEG.
EPASR*	United States Environmental Protection Agency, Office of Pesticides and Toxic Substances. (U.S. Environmental Protection Agency, 401 M St., SW, Washington, DC 20460) History unknown.
FEREAC	Federal Register. (U.S. Government Printing Office, Supt. of Documents, Washington, DC 20402) V.1- 1936-
GISAAA	Gigiena i Sanitariya. For English translation, see HYSAAV. (V/O Mezhdunarodnaya Kniga, 113095 Moscow, USSR) V.1- 1936-
HPCQA4	Human Pathology. (W.B. Saunders Co., W. Washington Sq., Philadelphia, PA 19105) V.1- 1970-
HUTOX*	
IYKEDH	Iyakuhin Kenkyu. Study of Medical Supplies. (Nippon Koteisho Kyokai, 12-15, 2-chome, Shibuya, Shibuya-ku, Tokyo 150, Japan) V.1- 1970-
JACTDZ	Journal of the American College of Toxicology. (Mary Ann Liebert, Inc., 1651 Third Ave., New York, NY 10128) V.1-12, 1982-1993. Discontinued.
JAPTO*	Journal of Applied Toxicology (John Wiley & Sons, Ltd., Oldlands Way Bognor Regis West Sussex, PO22 9SA England) V.1- 1981-
JTEHD6	Journal of Toxicology and Environmental Health. (Hemisphere Pub., 1025 Vermont Ave., NW, Washington, DC 20005) V.1- 1975/76-
MUREAV	Mutation Research. (Elsevier Science Pub. B.V., POB 211, 1000 AE Amsterdam, Netherlands) V.1- 1964-
MUTAEX	Mutagenesis. (Oxford Univ. Press, Pinkhill House, Southfield Road, Eynsham, Oxford OX8 1JJ, UK) V.1- 1986-
NIIRDN	Drugs in Japan (Ethical Drugs). (Yakugyo Jiho Co., Ltd., Tokyo, Japan)
NIOSH*	National Institute of Occupational Safety and Health, U.S. Dept. of Health, Education, and Welfare, Reports and Memoranda.

NTIS**	National Technical Information Service. (Springfield, VA 22161) Formerly U.S. Clearinghouse for Scientific & Technical Information.
NTPTR*	National Toxicology Program Technical Report Series. (Research Triangle Park, NC 27709) No.206-
OYYAA2	Oyo Yakuri. Pharmacometrics. (Oyo Yakuri Kenkyukai, CPO Box 180, Sendai 980-91, Japan) V.1- 1967-
SFCRAO	Collection of Papers Presented at the Annual Symposium on Fundamental Cancer Research. (Baltimore, MD) V.1-29, 1946-76. For publisher information, see AFCPDR.
TJADAB	Teratology, The International Journal of Abnormal Development. (Alan R. Liss, Inc., 41 E. 11th St., New York, NY 10003) V.1- 1968-
TOLED5	Toxicology Letters. (Elsevier Science Pub. B.V., POB 211, 1000 AE Amsterdam, Netherlands) V.1- 1977-
TOXID9	Toxicologist. (Soc. of Toxicology, Inc., 475 Wolf Ledge Parkway, Akron, OH 44311) V.1- 1981-
TXCYAC	Toxicology. (Elsevier Scientific Pub. Ireland, Ltd., POB 85, Limerick, Ireland) V.1- 1973-
UCDS**	Union Carbide Data Sheet. (Union Carbide Corp., 39 Old Ridgebury Rd., Danbury, CT 06817)
VCVGK*	"Vrednie chemichescie veshestva, galogen I kislorod sodergashie organicheskie soedinenia". (Hazardous substances. Galogen and oxygen containing substances), Bandman A.L. et al., Chimia, 1994.

Used in leather tanning and in embalming fluids and as a germicide and crosslinking agent

NIOSH PROFILE (ALDEHYDES), SRC, 4/78

NIOSH PROFILE (GLUTARALDEHYDE), SRC, 4/81

NIOSH PROFILE (ALDEHYDES), SRI, 2/77

RTECS Compound Description:
Tumorigen
Mutagen
Reproductive Effector
Human Data
Hormone
Primary Irritant

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Glutaraldehyde

MSDS # 313.00

ScholAR Chemistry

Section 1: Product and Company Identification

Glutaraldehyde

Synonyms/General Names: Glutaraldehyde solution
Product Use: For educational use only
Manufacturer: Columbus Chemical Industries, Inc., Columbus, WI 53925.

24 Hour Emergency Information Telephone Numbers

CHEMTREC (USA): 800-424-9300 **CANUTEC (Canada): 613-424-6666**

ScholAR Chemistry; 5100 W. Henrietta Rd, Rochester, NY 14586; (866) 260-0501; www.Scholarchemistry.com

Section 2: Hazards Identification

Clear, colorless to pale yellow liquid; sweet, floral odor.

HMIS (0 to 4)

Health	**3**
Fire Hazard	**0**
Reactivity	**1**

WARING! Highly toxic by ingestion, inhalation, and skin absorption. Corrosive to all body tissue –avoid all contact with body tissues.
Target organs: None known.

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Section 3: Composition / Information on Ingredients

Glutaraldehyde (111-30-8), 25%. Water (7732-18-5), 75%.

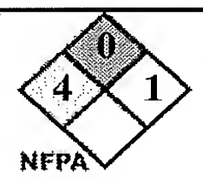
Section 4: First Aid Measures

Always seek professional medical attention after first aid measures are provided.

Eyes: Immediately flush eyes with excess water for 15 minutes, lifting lower and upper eyelids occasionally.
Skin: Immediately flush skin with excess water for 15 minutes while removing contaminated clothing.
Ingestion: Call Poison Control immediately. ***Do not induce vomiting***. Rinse mouth with cold water. Give victim 1-2 cups of water or milk to drink.
Inhalation: Remove to fresh air. If not breathing, give artificial respiration.

Section 5: Fire Fighting Measures

Nonflammable solution. When heated to decomposition, emits acrid fumes.
Protective equipment and precautions for firefighters: Use foam or dry chemical to extinguish fire. Firefighters should wear full fire fighting turn-out gear and respiratory protection (SCBA). Cool container with water spray. Material is not sensitive to mechanical impact or static discharge.



Section 6: Accidental Release Measures

Use personal protection recommended in Section 8. Isolate the hazard area and deny entry to unnecessary and unprotected personnel. Remove all ignition sources and ventilate area. Contain spill with sand or absorbent material and place material in a sealed bag or container for disposal. Wash spill area after pickup is complete. See Section 13 for disposal information.

Section 7: Handling and Storage Blue

Handling: Use with adequate ventilation and do not breathe dust or vapor. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly after handling.
Storage: Store in Toxic Storage Area [Blue Storage] with other toxic material. Store in a dedicated poison cabinet. Store in a cool, dry, well-ventilated, locked store room away from incompatible materials.

Section 8: Exposure Controls / Personal Protection

Use ventilation to keep airborne concentrations below exposure limits. Have approved eyewash facility, safety shower, and fire extinguishers readily available. Wear chemical splash goggles and chemical resistant clothing such as gloves and aprons. Wash hands thoroughly after handling material and before eating or drinking. Use NIOSH-approved respirator with an acid/organic cartridge. Exposure guidelines Glutaraldehyde: OSHA PEL: N/A and ACGIH TLV: 0.05 ppm ceiling, STEL: 0.2 mg/m^3 ceiling.

Section 9: Physical and Chemical Properties

Molecular formula	$HCO(CH_2)_3CHO$.	**Appearance**	Clear, colorless to pale yellow liquid.
Molecular weight	100.12.	**Odor**	Sweet, floral odor.
Specific Gravity	1.062 g/mL @ 20°C.	**Odor Threshold**	N/A.
Vapor Density (air=1)	3.5.	**Solubility**	Completely soluble in water.
Melting Point	-6°C.	**Evaporation rate**	> 1 *(Butyl acetate = 1).*
Boiling Point/Range	101°C.	**Partition Coefficient**	N/A *(log P_{OW}).*
Vapor Pressure (20°C)	N/A.	**pH**	N/A.
Flash Point:	N/A.	**LEL**	N/A.
Autoignition Temp.:	N/A.	**UEL**	N/A.

N/A = Not available or applicable

Section 10: Stability and Reactivity

Avoid heat and ignition sources.
Stability: Stable under normal conditions of use and storage.
Incompatibility: Strong oxidizers, reducing agents, acids and alkalis.
Shelf life: Indefinite if stored properly.

Section 11: Toxicology Information

Acute Symptoms/Signs of exposure: ***Eyes***: Redness, tearing, itching, burning, damage to cornea, conjunctivitis, loss of vision. ***Skin***: Redness, blistering, burning, itching, tissue destruction with slow healing. ***Ingestion***: Nausea, vomiting, burning, diarrhea, ulceration, convulsions, shock. ***Inhalation***: Coughing, wheezing, shortness of breath, headache, spasm, inflammation and edema of bronchi, pneumonitis.
Chronic Effects: Repeated/prolonged skin contact may cause thickening, blackening or cracking. Repeated eye exposure may cause corneal erosion or loss of vision. **Sensitization:** Skin sensitizer
Glutaraldehyde: LD50 [oral, rat]; 134 mg/kg; LC50 [rat]; N/A; LD50 Dermal [rabbit]; 500 mg/24hr/Severe
Material has not been found to be a carcinogen nor produce genetic, reproductive, or developmental effects.

Section 12: Ecological Information

Ecotoxicity (aquatic and terrestrial): Toxic to beneficial microorganisms (e.g. soil and sewage treatment microorganisms). Do not release to the environment.

Section 13: Disposal Considerations

Check with all applicable local, regional, and national laws and regulations. Local regulations may be more stringent than regional or national regulations. Small amounts of this material may be suitable for sanitary sewer disposal.

Section 14: Transport Information

DOT Shipping Name:	Not regulated by DOT.	**Canada TDG:**	Not regulated by TDG.
DOT Hazard Class:		**Hazard Class:**	
Identification Number:		**UN Number:**	

Section 15: Regulatory Information

EINECS: Listed (203-856-5). **WHMIS Canada:** D1B, D2B, E: Toxic material .
TSCA: All components are listed or are exempt. **California Proposition 65:** Not listed.
The product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

Section 16: Other Information

Current Issue Date: January 23, 2009
Disclaimer: Scholar Chemistry and Columbus Chemical Industries, Inc., ("S&C") believes that the information herein is factual but is not intended to be all inclusive. The information relates only to the specific material designated and does not relate to its use in combination with other materials or its use as to any particular process. Because safety standards and regulations are subject to change and because S&C has no continuing control over the material, those handling, storing or using the material should satisfy themselves that they have current information regarding the particular way the material is handled, stored or used and that the same is done in accordance with federal, state and local law. ***S&C makes no warranty, expressed or implied, including (without limitation) warranties with respect to the completeness or continuing accuracy of the information contained herein or with respect to fitness for any particular use.***

 1/23/2009

HIGHLY TOXIC / ACUTELY TOXIC MATERIALS LIST

This list is NOT all inclusive and may not contain all potential Highly Acute Toxins. Reference the MSDS of the substance for Toxicity warnings. Pharmaceuticals and biological substances can also present Highly Acute Hazards.

If a substance is on this list or the manufacturer of the substance indicates that it is a Highly Acute Toxin, follow the correct handling, storage and regulatory requirements described in the SBMS Working With Chemicals Subject Area as they pertain to *Particularly Hazardous Substances.*

OSHA defines substances that are considered to have a High degree of Acute Toxicity as those substances which are highly toxic or toxic as defined below and may be fatal or cause damage to target organs as a result of a single exposure or exposures of short duration.

Highly Toxic	LD(50) equal to 50 milligrams or less per kilogram of body weight when administered orally to albino rats. LD(50) equal to 200 milligrams or less per kilogram of body weight when administered by continuous contact for 24 hours or less with the bare skin of albino rabbits. LC(50) in air of 200 ppm by volume or less of gas or vapor, or 2 mg/L or less of mist, fume, or dust, when administered by continuous inhalation for one hour or less to albino rats.
Toxic	LD(50) of more than 50 milligrams per kilogram but not more than 500 milligrams per kilogram of body weight when administrered orally to albino rats. LD(50) of more than 200 milligrams per kilogram but not more then 1,000 milligrams per kilogram of body weight when administered by continuous contact for 24 hours or less with the bare skin of albino rabbits. LC(50) in air of more than 200 ppm but not more than 2,000 ppm by volume of gas, vapor, or more than two milligrams per liter but not more than 20 milligrams per liter of mist, fume, or dust, when administered by continuous inhalation for one hour or less to albino rats.

Chemical Name	CAS	Oral Rat LD50	Skin Rabbit LD50	Inh Rat LC50
(-)-N-((5-CHLORO-8-HYDROXY-3-METHYL-1-OXO-7-ISOCHROMANYL)CARBONYL)-3-PHENYLALANINE	000303-47-9	20 mg/kg	unknown	unknown
(24R)-HYDROXYCALCIDIOL	055721-11-4	>10 mg/kg	unknown	unknown
(4-AMINOBUTYL)DIETHOXYMETHYLSILANE	003037-72-7	unknown	45 mg/kg	unknown
(E)-N,N-DIMETHYL-4-STILBENAMINE	000838-95-9	50 mg/kg	unknown	unknown
(trans-4)-DICHLORO(4,4-DIMETHYLZINC 5 ((((METHYLAMINO)CARBONYL)OXY)IMINO) PENTANENITRILE)	058270-08-9	9 mg/kg	unknown	unknown
1-((4-METHOXY(1,1'-BIPHENYL)-3-YL)METHYL)	066839-	28 mg/kg	unknown	unknown

PYRROLIDINE	98-3			
1,(5,5,7,7-TETRAMETHYL-2-OCTANYL)-2-METHYL-5-ETHYLPYRIDINIUM CHLORIDE	010031-58-0	unknown	71 mg/kg	unknown
1,1,3,3-TETRACHLOROACETONE	000632-21-3	unknown	80 mg/kg	unknown
1,1'-BI(ETHYLENE OXIDE)	001464-53-5	unknown	80 mg/kg	90 ppm
1,2-DIBROMO-3-CHLOROPROPANE	000096-12-8	unknown	unknown	103 ppm
1,3,4,5,6,8,8-OCTACHLORO-1,3,3a,4,7,7a-HEXAHYDRO-4,7-METHANOISOBENZOFURAN	000297-78-9	unknown	12 mg/kg	unknown
1,3,4-METHENO-1H-CYCLOBUTA(c,d)-PENTALENE-2-LEVULINIC ACID, 1,1A,3,3A,4,5,5A,5B,6-DECACHLOROOCTAHYDRO-2-HYDROXY-, Ethyl Ester	004234-79-1	unknown	188 mg/kg	unknown
1,3,4-TRIPHENYLPYRAZOLE-5-ACETIC ACID SODIUM SALT	078218-49-2	13 mg/kg	unknown	unknown
1,3,5-TRIACRYLOYLHEXAHYDROTRIAZINE	000959-52-4	unknown	70 mg/kg	unknown
1,3-PROPANEDIAMINE	000109-76-2	unknown	200 mg/kg	unknown
1,4-PHENYLENEDIISOTHIOCYANIC ACID	004044-65-9	21 mg/kg	unknown	unknown
10,10'-OXIDIPHENOXARSINE	000058-36-6	40 mg/kg	unknown	unknown
1-ADRENALINE CHLORIDE	000055-31-2	24 mg/kg	unknown	unknown
1-Chloro-2,3-epoxy-propane (epilchlorohydrin)	000106-89-8	90 mg/kg	10 mg/kg	250 ppm
1-CHLORO-2,4-DINITROBENZENE	000097-00-7	unknown	130 mg/kg	unknown
1-CYCLOHEXYL-2-PYRROLIDINONE	006837-24-7	unknown	unknown	120 ppm
1-DIMETHYLCARBAMOYL-5-METHYL-3-PYRAZOLYL DIMETHYLCARBAMATE	000644-64-4	25 mg/kg	unknown	unknown
1-EMETINE DIHYDROCHLORIDE	000316-42-7	12 mg/kg	unknown	unknown
1-METHYL-4-PHENYLPYRIDINIUM CHLORIDE	039794-99-5	35 mg/kg	unknown	unknown
1-NITRO-10-(DIMETHYLAMINOETHYL)-9-ACRIDONE HYDROCHLORIDE	024268-87-9	41 mg/kg	unknown	unknown
1-NITRO-9-(DIMETHYLAMINO)-ACRIDINE HYDROCHLORIDE	028743-45-5	24 mg/kg	unknown	unknown
1-PHENYL-2-THIOUREA	000103-85-5	3 mg/kg	unknown	unknown
1-PHENYLPIPERAZINE	000092-54-6	unknown	140 mg/kg	unknown
1-VINYL AZIRIDINE	005628-99-9	unknown	20 mg/kg	unknown
2-((4-AMINO-3-METHYLPHENYL)ETHYLAMINO) ETHANOL SULFATE	025646-77-9	35 mg/kg	unknown	unknown
	000112-		125	

2-(2-BUTOXY ETHOXY)ETHYL THIOCYANATE	56-1	unknown	mg/kg	unknown
2-(DIETHOXYPHOSPHINYLIMINO)-4-METHYL-1,3-DITHIOLANE	000950-10-7	9 mg/kg	unknown	unknown
2-(N,N-BIS(2-CHLOROETHYL)AMINOPHENYL) ACETIC ACID BUTYL ESTER	066232-25-5	20 mg/kg	unknown	unknown
2-(N,N-BIS(2-CHLOROETHYL)AMINOPHENYL)ACETIC ACID TETRADECYL ESTER	066232-28-8	46 mg/kg	unknown	unknown
2-(N-METHYL-N-NITROSO)AMINOACETONITRILE	003684-97-7	45 mg/kg	unknown	unknown
2,2-BIS(CHLOROMETHYL)-1,3-PROPANEDIOL SULFATE	012712-28-6	20 mg/kg	unknown	unknown
2,2-DIMETHYL-1,3-BENZODIOX-4-OL METHYLCARBAMATE	022781-23-3	40 mg/kg	unknown	unknown
2,2'-THIOBIS(4,6-DICHLOROPHENOL)	000097-18-7	7 mg/kg	unknown	unknown
2,3,4,5-TETRACHLOROTHIOPHENE	006012-97-1	unknown	unknown	146 ppm
2,3-DICHLORO PROPIONALDEHYDE	010140-89-3	unknown	78 mg/kg	unknown
2,3-DICHLOROHEXAFLUOROBUTENE-2	000303-04-8	unknown	unknown	16 ppm
2,3-DICHLOROPROPANOL	000616-23-9	unknown	200 mg/kg	unknown
2,3-DIHYDRO-2-METHYLBENZOPYRANYL-7,N-METHYLCARBAMATE	001563-67-3	43 mg/kg	unknown	unknown
2,3-DIMETHYL-7-METHOXY-8-(MORPHOLINOMETHYL)CHROMONE HYDROCHLORIDE	063938-21-6	44 mg/kg	unknown	unknown
2,4,5-TRIBROMOIMIDAZOLE	002034-22-2	34 mg/kg	unknown	unknown
2,4'-DIFLUOROACETANILIDE	000404-42-2	2 mg/kg	unknown	unknown
2,4-DIHYDROXY-3,3-DIMETHYLBUTYRONITRILE	010232-92-5	unknown	130 mg/kg	unknown
2,4-DIMETHYL-1,3-DITHIOLANE-2-CARBOXALDEHYDE O-(METHYLCARBAMOYL) OXIME	026419-73-8	1 mg/kg	unknown	unknown
2,4-DINITROPHENOL	000051-28-5	30 mg/kg	unknown	unknown
2-ACETOXYACRYLONITRILE	003061-65-2	unknown	140 mg/kg	unknown
2-AMINO-5-PHENYL-OXAZOLINE FORMATE	013425-22-4	25 mg/kg	unknown	unknown
2-ANILINOETHANOL	000122-98-5	unknown	63 mg/kg	unknown
2-BENZHYDRYL-3-HYDROXY-N-METHYLPIPERIDINE HYDROCHLORIDE	019974-69-7	1 mg/kg	unknown	unknown
2-BUTYLENE DICHLORIDE	000110-57-6	unknown	unknown	86 ppm
2-CARBOETHOXY-1-METHYLVINYL-DIETHYLPHOSPHATE	005675-57-0	22 mg/kg	unknown	unknown

2-CHLORO-1,1,1,4,4,4-HEXAFLUOROBUTENE-2	000400-44-2	unknown	unknown	3 ppm
2-CHLORO-1,1,2-TRIFLUOROETHYL METHYL ETHER	000425-87-6	unknown	200 mg/kg	unknown
2-CHLORO-4,5-DIMETHYLPHENYL METHYLCARBAMATE	000671-04-5	30 mg/kg	unknown	unknown
2-CHLOROETHYL PARAOXON	000311-44-4	37 mg/kg	unknown	unknown
2-CHLORO-N-METHYL-N-NITROSOETHYLAMINE	016339-16-5	22 mg/kg	unknown	unknown
2-CHLOROPYRIDINE	000109-09-1	unknown	64 mg/kg	unknown
2-CHLOROVINYL DIETHYL PHOSPHATE	000311-47-7	10 mg/kg	unknown	22 ppm
2-CYCLOHEXEN-1-ONE	000930-68-7	unknown	70 mg/kg	unknown
2-FLUORO-2-PROPEN-1-OL	005675-31-0	unknown	3 mg/kg	unknown
2-FLUOROETHANOL	000371-62-0	5 mg/kg	unknown	unknown
2-HYDROXY-3-BUTENENITRILE	005809-59-6	unknown	unknown	16 ppm
2-ISOCYANATOETHYL METHACRYLATE	030674-80-7	unknown	unknown	4 ppm
2-METHOXYETHYLMERCURY CHLORIDE	000123-88-6	22 mg/kg	unknown	unknown
2-METHYLLACTONITRILE	000075-86-5	unknown	17 mg/kg	unknown
2-PENTENENITRILE, (Z)-	025899-50-7	unknown	>200 mg/kg	unknown
2-sec-BUTYL-4,6-DINITROPHENOL	000088-85-7	25 mg/kg	80 mg/kg	unknown
2-tert-BUTYL-5-METHYL-4,6-DINITROPHENYL ACETATE	002487-01-6	42 mg/kg	unknown	unknown
3-(1-METHYLPROPYL)-6-CHLOROPHENYL METHYLCARBAMATE	002917-19-3	50 mg/kg	unknown	unknown
3-(2-AMINOBUTYL)INDOLE ACETATE	000118-68-3	49 mg/kg	unknown	unknown
3-(2-AMINOPROPYL)INDOLE	000299-26-3	22 mg/kg	unknown	unknown
3-(a-ACETONYLFURFURYL)-4-HYDROXYCOUMARIN	000117-52-2	25 mg/kg	unknown	unknown
3-(DIMETHOXYPHOSPHINYLOXY)-N-METHYL-N-METHOXY-cis-CROTONAMIDE	025601-84-7	2 mg/kg	107 mg/kg	unknown
3,4-DIPHENYL-1-ISOBUTYLPYRAZOLE-5-ACETIC ACID SODIUM SALT		46 mg/kg	unknown	unknown
3,4-EPOXYCYCLOHEXYLMETHYL 3,4-EPOXYCYCLOHEXANE CARBOXYLATE	002386-87-0	unknown	20 mg/kg	unknown
3,5-DIMETHYL-1-(TRICHLOROMETHYLMERCAPTO) PYRAZOLE	025724-50-9	unknown	200 mg/kg	unknown
3,5-DIMETHYL-4-METHYLTHIOPHENYL-N-	002032-			

METHYLCARBAMATE	65-7	15 mg/kg	unknown	unknown
3-ACETOPYRIDINE	000350-03-8	46 mg/kg	unknown	unknown
3-BUTEN-2-ONE	000078-94-4	31 mg/kg	unknown	unknown
3-CHLORO-2-FLUOROPROPENE	006186-91-0	unknown	200 mg/kg	unknown
3-CHLORO-6-CYANO-2-NORBORNANONE-o-(METHYLCARBAMOYL)OXIME	015271-41-7	19 mg/kg	unknown	unknown
3-CHLOROPROPYL-n-OCTYLSULFOXIDE	003569-57-1	unknown	8 mg/kg	unknown
3-PYRROLIDINOMETHYL-4-HYDROXYBIPHENYL	066839-97-2	30 mg/kg	unknown	unknown
4-(DIMETHYLAMINE)-3,5-XYLYL-N-METHYLCARBAMATE	000315-18-4	14 mg/kg	unknown	unknown
4,5-EPOXY-2-PENTENAL	064011-46-7	unknown	40 mg/kg	unknown
4,6-DINITRO-o-CRESOL SODIUM SALT	002312-76-7	26 mg/kg	unknown	unknown
4,7-PHENANTHROLINE-5,6-DIONE	000084-12-8	5 mg/kg	unknown	unknown
4-AMINO-2,2,5,5-TETRAKIS(TRIFLUOROMETHYL)-3-IMIDAZOLINE	023757-42-8	19 mg/kg	unknown	unknown
4-AMINOPYRIDINE	000504-24-5	21 mg/kg	unknown	unknown
4-CHLOROPHENYL THIOUREA	003696-23-9	15 mg/kg	unknown	unknown
4-DIMETHYLAMINE m-CRESYL METHYLCARBAMATE	002032-59-9	30 mg/kg	unknown	unknown
4-HEXEN-1-YN-3-OL	010138-60-0	34 mg/kg	unknown	unknown
4-HEXEN-1-YN-3-ONE	013061-80-8	unknown	100 mg/kg	unknown
5,5'-DICHLORO-2,2'-DIHYDROXY-3,3'-DINITROBIPHENYL	010331-57-4	10 mg/kg	unknown	unknown
5-AMINO-1-BIS(DIMETHYLAMIDE)PHOSPHORYL-3-PHENYL-1,2,4-TRIAZOLE	001031-47-6	20 mg/kg	unknown	unknown
5-AMINOMETHYL-3-ISOXYZOLE	002763-96-4	45 mg/kg	unknown	unknown
5-DIMETHYLAMINO-4-TOLYL METHYLCARBAMATE	014144-91-3	46 mg/kg	unknown	unknown
5-ETHYL-5-(1-METHYL-2-BUTENYL)BARBITURIC ACID	017013-35-3	20 mg/kg	unknown	unknown
5-NORBORNENE-2,3-DICARBOXIMIDE, 5-(a-HYDROXY-a-2-PYRIDYLBENZYL)-N-(2-METHOXYETHYL)-7-(a-2-PYRIDYLBENZYLIDENE)-, ENDO-	004634-47-3	9 mg/kg	unknown	unknown
6-CHLORO-5-CYCLOHEXYL-1-INDANCARBOXYLIC ACID	028968-07-2	41 mg/kg	unknown	unknown
7-DEAZAINOSINE	002862-16-0	26 mg/kg	unknown	unknown

8-b-((METHYLTHIO)METHYL)-6-PROPYLERGOLINE METHANESULFONATE	066104-23-2	15 mg/kg	unknown	unknown
ACEMETACIN	053164-05-9	24 mg/kg	unknown	unknown
ACETALDOL	000107-89-1	unknown	140 mg/kg	unknown
ACETIC ACID-2-METHYL-2-PROPENE-1,1-DIOL DIESTER	010476-95-6	unknown	44 mg/kg	unknown
ACETIC ACID-4,6-DINITRO-o-CRESYL ESTER	018461-55-7	46 mg/kg	unknown	unknown
ACETOXYPHENYLMERCURY	000062-38-4	41 mg/kg	unknown	unknown
ACETOXYTRIETHYLSTANNANE	001907-13-7	4 mg/kg	unknown	unknown
ACETYL THIOUREA	000591-08-2	50 mg/kg	unknown	unknown
ACROLEIN	000107-02-8	46 mg/kg	unknown	unknown
ACROLEIN DIACETATE	000869-29-4	35 mg/kg	unknown	unknown
ACRYLIC ACID ETHYLHEXYL ESTER mixed with HYDROXYETHYL ESTER (50:50)		unknown	170 mg/kg	unknown
a-CYCLOPIAZONIC ACID	018172-33-3	36 mg/kg	unknown	unknown
ALDOXYCARB	001646-88-4	20 mg/kg	200 mg/kg	unknown
ALDRIN	000309-00-2	39 mg/kg	unknown	unknown
ALLYL ALCOHOL	000107-18-6	64 mg/kg	45 mg/kg	165 ppm
ALLYL ISOTHIOCYANATE	000057-06-7	unknown	88 mg/kg	unknown
ALLYLAMINE	000107-11-9	unknown	35 mg/kg	unknown
AMETYCIN	000050-07-7	30 mg/kg	unknown	unknown
AMIDEFRINE MESYLATE	001421-68-7	13 mg/kg	unknown	unknown
AMIPURIMYCIN HYDRATE		20 mg/kg	unknown	unknown
AMITON OXALATE	003734-97-2	3 mg/kg	unknown	unknown
ANGUIDIN	002270-40-8	7 mg/kg	unknown	unknown
ANTIMYCIN	011118-72-2	28 mg/kg	unknown	unknown
ANTU	000086-88-4	6 mg/kg	unknown	unknown
ARSENIC ACID, CALCIUM SALT (2:3)	007778-44-1	20 mg/kg	unknown	unknown
ARSENIC PENTOXIDE	001303-28-2	8 mg/kg	unknown	unknown

ARSINE	007784-42-1	unknown	unknown	unknown
AZINPHOS METHYL	000086-50-0	7 mg/kg	unknown	unknown
BENZEDRINE	000300-62-9	30 mg/kg	unknown	unknown
BENZENE HEXACHLORIDE-g-isomer	000058-89-9	unknown	50 mg/kg	unknown
Benzotrichloride	000098-07-7	unknown	20 mg/kg	unknown
Benzyl Chloride	000098-88-4	unknown	unknown	150 ppm
b-FLUOROETHYLIC ESTER of XENYLACETIC ACID	004242-33-5	unknown	7 mg/kg	unknown
BIS(2,5-ENDOMETHYLENECYCLOHEXYLMETHYL) AMINE	010171-76-3	unknown	110 mg/kg	unknown
BIS(2-CHLOROETHYL)ETHYLAMINE	000538-07-8	unknown	15 mg/kg	unknown
BIS(2-CHLOROETHYL)METHYLAMINE HYDROCHLORIDE	000055-86-7	10 mg/kg	unknown	unknown
BIS(2-CHLOROETHYL)PHOSPHITE	001070-42-4	unknown	141 mg/kg	unknown
BIS(2-CHLOROETHYL)SULFIDE	000505-60-2	unknown	40 mg/kg	unknown
BIS(b-CHLOROETHYL)METHYLAMINE	000051-75-2	10 mg/kg	12 mg/kg	unknown
BIS(CHLOROMETHYL) ETHER	000542-88-1	unknown	unknown	7 ppm
BIS(DIETHYLTHIO)CHLORO METHYL PHOSPHONATE	034491-12-8	35 mg/kg	unknown	unknown
BIS(DIMETHYLAMIDO)FLUORO PHOSPHATE	000115-26-4	1 mg/kg	unknown	unknown
BIS(ETHYLMERCURI) PHOSPHATE	002440-45-1	30 mg/kg	unknown	unknown
BIS(METHYLMERCURIC)SULFATE	003810-81-9	50 mg/kg	unknown	unknown
BISPHENOL A DIGLYCIDYL ETHER	001675-54-3	unknown	20 mg/kg	unknown
BLASTICIDIN S	002079-00-7	16 mg/kg	unknown	unknown
b-PROPIOLACTONE	000057-57-8	unknown	unknown	25 ppm
BROMETHALINE	063333-35-7	2 mg/kg	unknown	unknown
BUTOPHEN	006365-83-9	45 mg/kg	unknown	unknown
BUTRIZOL	016227-10-4	50 mg/kg	unknown	unknown
BUTYL PHOSPHOROTRITHIOATE	000078-48-8	unknown	97 mg/kg	unknown
BUTYL-2-BUTOXYCYCLOPROPANE-1-	063937-		110	

CARBOXYLATE	32-6	24 mg/kg	mg/kg	unknown
BUTYRONITRILE	000109-74-0	50 mg/kg	unknown	unknown
C.I. BASIC RED 12	006320-14-5	18 mg/kg	unknown	unknown
CALCIUM CYANIDE	000592-01-8	39 mg/kg	unknown	unknown
CARBACHOL CHLORIDE	000051-83-2	40 mg/kg	unknown	unknown
CARBOFURAN	001563-66-2	5 mg/kg	unknown	unknown
CHLORACETONE	000078-95-5	100 mg/kg	141 mg/kg	262 ppm
CHLORFENVINFOS	000470-90-6	10 mg/kg	unknown	unknown
CHLORINATED CAMPHENE	008001-35-2	50 mg/kg	unknown	unknown
Chlorine	007782-50-5	unknown	unknown	293 ppm
CHLORINE TRIFLUORIDE	007790-91-2	unknown	unknown	unknown
CHLORMEPHOS	024934-91-6	7 mg/kg	unknown	unknown
CHLORO DIISOBUTYL ALUMINUM	001779-25-5	unknown	unknown	67 ppm
CHLOROETHYL MERCURY	000107-27-7	40 mg/kg	unknown	unknown
CHLOROMETHYL METHYL ETHER	000107-30-2	unknown	unknown	55 ppm
CHLOROPEPTIDE		5 mg/kg	unknown	unknown
CHLOROPHACINONE	003691-35-8	unknown	200 mg/kg	unknown
CHLOROPICRIN	000076-06-2	250 mg/kg	unknown	14 ppm
CHLORTHIOPHOS	060238-56-4	unknown	50 mg/kg	unknown
CHOLECALCIFEROL	000067-97-0	42 mg/kg	unknown	unknown
CLIDANAC	034148-01-1	41 mg/kg	unknown	unknown
COUMAPHOS	000056-72-4	13 mg/kg	unknown	unknown
Crotonaldehyde	004170-30-3	206 mg/kg	unknown	unknown
CUPRIC ACETOARSENITE	012002-03-8	22 mg/kg	unknown	unknown
CYANODIMETHYLARSINE	000683-45-4	50 mg/kg	unknown	unknown
CYANOMETHYL ACETATE	001001-55-4	32 mg/kg	43 mg/kg	unknown

CYANOPHOS	002636-26-2	25 mg/kg	unknown	unknown
CYCLIC NEOPENTANETETRAYL BIS(2,4-DI-tert-BUTYLPHENYL)ESTER PHOSPHOROUS ACID	026741-53-7	unknown	>200 mg/kg	unknown
CYCLOHEXIMIDE	000066-81-9	2 mg/kg	unknown	unknown
CYCLOPENTADIENYLMANGANESE TRICARBONYL	012079-65-1	22 mg/kg	unknown	unknown
DACAMOX	039196-18-4	unknown	39 mg/kg	unknown
d-AMPHETAMINE	000051-64-9	38 mg/kg	unknown	unknown
DANITOL	039515-41-8	18 mg/kg	unknown	unknown
d-BENZEDRINE SULFATE	000051-63-8	32 mg/kg	unknown	unknown
d-CARVONE	002244-16-8	unknown	4 mg/kg	unknown
DECABORANE	017702-41-9	unknown	71 mg/kg	46 ppm
DECAMETHRINE	052918-63-5	30 mg/kg	unknown	unknown
DEMETON-O + DEMETON-S	008065-48-3	unknown	24 mg/kg	unknown
DEMETON-O-METHYL SULFOXIDE	000301-12-2	30 mg/kg	unknown	unknown
DEMETON-S-METHYL	000919-86-8	30 mg/kg	unknown	unknown
DESOXYEPHEDRINE HYDROCHLORIDE	000300-42-5	29 mg/kg	unknown	unknown
DI(2-CHLOROETHYL) ACETAL	014689-97-5	unknown	200 mg/kg	unknown
DI-2-CHLOROETHYL MALEATE	063917-06-6	unknown	140 mg/kg	unknown
DIACETOXYDIBUTYL STANNANE	001067-33-0	32 mg/kg	unknown	unknown
DIALIFOR	010311-84-9	5 mg/kg	unknown	unknown
DIANHYDROGALACTITOL	023261-20-3	14 mg/kg	unknown	unknown
DIAZINON	000333-41-5	unknown	180 mg/kg	unknown
DIBORANE	019287-45-7	unknown	unknown	40 ppm
DIBROMOPHENYLARSINE	000696-24-2	unknown	4 mg/kg	unknown
DIBUTYL LEAD DIACETATE	002587-84-0	34 mg/kg	unknown	unknown
DICHLORO(2-CHLOROVINYL)ARSINE OXIDE	000333-25-5	5 mg/kg	unknown	unknown
	007572-			

DICHLOROACETYLENE	29-4	unknown	unknown	unknown
DICHLOROPHENYLARSINE	000696-28-6	unknown	5 mg/kg	unknown
DICHLOROTETRAFLUOROACETONE	000127-21-9	unknown	146 mg/kg	unknown
DICHLORVOS	000062-73-7	17 mg/kg	107 mg/kg	unknown
DICROTOPHOS	000141-66-2	13 mg/kg	168 mg/kg	unknown
DICUMENE CHROMIUM	012001-89-7	unknown	22 mg/kg	unknown
DIETHYL CHLOROPHOSPHATE	000814-49-3	11 mg/kg	unknown	unknown
DIETHYLAMINOETHYL ACRYLATE	002426-54-2	unknown	200 mg/kg	unknown
DIFLUOROPHENYLARSINE	000368-97-8	unknown	4 mg/kg	unknown
DIGLYCIDYL ETHER	002238-07-5	450 mg/kg	unknown	1500 mg/kg
DIHEXYLAMINE	000143-16-8	unknown	170 mg/kg	unknown
DIMEFLINE	001165-48-6	40 mg/kg	unknown	unknown
DIMEFLINE HYDROCHLORIDE		14 mg/kg	unknown	unknown
DIMETHOATE OXYGEN ANALOG	001113-02-6	30 mg/kg	unknown	unknown
DIMETHYL PARANITROPHENYL THIONOPHOSPHATE	003820-53-9	43 mg/kg	unknown	unknown
DIMETHYL PHOSPHATE ESTER with 2-CHLORO-N-ETHYL-3-HYDROXYCROTONAMIDE	013171-22-7	37 mg/kg	unknown	unknown
DIMETHYL PHOSPHATE ESTER with 2-CHLORO-N-METHYL-3-HYDROXYCROTONAMIDE	034491-04-8	33 mg/kg	unknown	unknown
Dimethyl Sulfate	000077-78-1	205 mg/kg	5 mg/kg	45 mg/m3
DIMETHYL-1,2,2,2-TETRACHLOROETHYL PHOSPHATE	003862-21-3	14 mg/kg	unknown	unknown
DIMETHYLAMINOACETONITRILE	000926-64-7	50 mg/kg	170 mg/kg	unknown
DIMETHYLCARBAMOYL CHLORIDE	000079-44-7	unknown	unknown	180 ppm
DIMETHYLTHIOMETHYLPHOSPHATE	000152-20-5	15 mg/kg	unknown	unknown
DINITRO-o-CRESOL	000534-52-1	10 mg/kg	unknown	unknown
DIOXATHION	000078-34-2	20 mg/kg	85 mg/kg	unknown
DIPHENYLIODONIUM HEXAFLUOROARSENATE (1-) DIPHENYLIODONIUM	062613-15-4	49 mg/kg	unknown	unknown
DIPHENYLTHIOUREA	000102-08-9	50 mg/kg	unknown	unknown

DISODIUM-3,6-ENDOXOHEXAHYDROPHTHALATE	000129-67-9	unknown	100 mg/kg	unknown
DISTIGMINE BROMIDE	015876-67-2	10 mg/kg	unknown	unknown
DISULFOTON	000298-04-4	4 mg/kg	unknown	unknown
DITHIOBIURET	000541-53-7	5 mg/kg	unknown	unknown
DITHIOLANE IMINOPHOSPHATE	000333-29-9	14 mg/kg	23 mg/kg	unknown
DIVINYL SULFONE	000077-77-0	32 mg/kg	22 mg/kg	unknown
D-KETOENDRIN	053494-70-5	10 mg/kg	unknown	unknown
dl-DIEPOXYBUTANE	000298-18-0	unknown	unknown	56 ppm
ENDOSULFAN	000115-29-7	18 mg/kg	90 mg/kg	unknown
ENDOSULFAN SULFATE	001031-07-8	18 mg/kg	unknown	unknown
ENDOTHAL	000145-73-3	38 mg/kg	unknown	unknown
ENDOTHION		23 mg/kg	unknown	unknown
ENDRIN	000072-20-8	3 mg/kg	unknown	unknown
EPN	002104-64-5	7 mg/kg	30 mg/kg	unknown
EPOXYHEPTACHLOR	001024-57-3	15 mg/kg	unknown	unknown
ERGOCHROME AA (2,2')-5-b,6-a,10-b-5',6'-a,10'-b	035287-69-5	22 mg/kg	unknown	unknown
Ethanolamine	000141-43-5	1720 mg/kg	1 mL/kg	unknown
ETHANOLMERCURY BROMIDE	023471-13-8	16 mg/kg	unknown	unknown
ETHION	000563-12-2	13 mg/kg	unknown	unknown
ETHYL DECABORANE	026747-87-5	unknown	unknown	23 ppm
ETHYL GUTHION	002642-71-9	7 mg/kg	unknown	unknown
Ethyl Mercuric Chloride	000107-27-7	58 mg/kg	uknown	unknown
ETHYL TRICHLOROPHENYLETHYLPHOSPHONOTHIOATE	000327-98-0	unknown	unknown	unknown
ETHYL(CHLOROETHYL)ANILINE	000092-49-9	unknown	200 mg/kg	unknown
ETHYLENE CHLOROHYDRIN	000107-07-3	71 mg/kg	67 mg/kg	290 mg/m3
ETHYLENEIMINE	000151-56-4	15 mg/kg	unknown	unknown

ETHYLMERCURIC PHOSPHATE	002235-25-8	48 mg/kg	unknown	unknown
FAMFOS	013171-21-6	8 mg/kg	80 mg/kg	unknown
FAMPHUR	000052-85-7	28 mg/kg	unknown	unknown
FENAMIPHOS	022224-92-6	8 mg/kg	178 mg/kg	unknown
FENAZAQUIN	120928-09-8	50 mg/kg	unknown	unknown
FENSULFOTHION	000115-90-2	2 mg/kg	unknown	unknown
FLEXOL PLASTICIZER 810	008036-63-3	unknown	20 mg/kg	unknown
FLUENETIL	004301-50-2	6 mg/kg	unknown	unknown
FLUOCINOLIDE	000356-12-7	14 mg/kg	unknown	unknown
FLUORINE	007782-41-4	unknown	unknown	185 ppm
FLUOROETHYL-O,O-DIETHYLDITHIOPHOSPHORYL-1-PHENYLACETATE	004681-36-1	5 mg/kg	unknown	unknown
FONOFOS	000944-22-9	3 mg/kg	25 mg/kg	unknown
FORCE	079538-32-2	22 mg/kg	unknown	unknown
FORMALDEHYDE, POLYMER with BENZENAMINE	025214-70-4	unknown	20 mg/kg	unknown
FUNICOLOSIN	011055-06-4	5 mg/kg	unknown	unknown
FUSARENONE X	023255-69-8	4 mg/kg	unknown	unknown
HEPTACHLOR	000076-44-8	40 mg/kg	unknown	unknown
HEXACHLOROCYCLOPENTADIENE	000077-47-4	1300 mg/kg	430 mg/kg	1.6 ppm
HEXAETHYL TETRAPHOSPHATE	000757-58-4	7 mg/kg	unknown	unknown
HEXAFLUORO ACETONE TRIHYDRATE	034202-69-2	unknown	113 mg/kg	unknown
HEXAFLUOROACETONE HYDRATE	010543-95-0	unknown	113 mg/kg	unknown
HEXAFLUORODICHLOROBUTENE	011111-49-2	unknown	unknown	16 ppm
HEXAMETHYLDITIN	000661-69-8	25 mg/kg	unknown	unknown
HICAL-2		unknown	104 mg/kg	unknown
HYDRAZINE	000302-01-2	unknown	91 mg/kg	unknown
	007783-			

HYDROGEN SELENIDE	07-5	unknown	unknown	unknown
Hydrogen Sulfide	007783-06-4	unknown	unknown	444 ppm
HYDROXYACETONITRILE	000107-16-4	16 mg/kg	5 mg/kg	unknown
HYDROXYTRIPHENYLSTANNANE	000076-87-9	46 mg/kg	unknown	unknown
IODOFORM	000075-47-8	unknown	unknown	165 ppm
IRON PENTACARBONYL	013463-40-6	unknown	240 mg/kg	unknown
ISODRIN	000465-73-6	7 mg/kg	unknown	unknown
ISOPHENPHOS	025311-71-1	28 mg/kg	162 mg/kg	unknown
ISOPHORONE DIISOCYANATE	004098-71-9	unknown	unknown	260 mg/m3
ISOPROPYL DIETHYLDITHIOPHOSPHORYLACETAMIDE	002275-18-5	8 mg/kg	unknown	unknown
ISOPROPYL PHOSPHOROFLUORIDATE	000055-91-4	5 mg/kg	unknown	unknown
ISOPROPYLMORPHOLINE	001331-24-4	unknown	100 mg/kg	unknown
ISOTHIOCYANATOMETHANE	000556-61-6	unknown	33 mg/kg	unknown
LACTONITRILE	000078-97-7	unknown	20 mg/kg	unknown
LEPTOPHOS	021609-90-5	19 mg/kg	unknown	unknown
LUCIJET	001716-09-2	14 mg/kg	unknown	unknown
MANGANESE TRICARBONYL METHYLCYCLOPENTADIENYL	012108-13-3	50 mg/kg	140 mg/kg	unknown
m-CUMENOL METHYLCARBAMATE	000064-00-6	29 mg/kg	40 mg/kg	unknown
Merbromin	000129-16-8	58 mg/kg	unknown	unknown
MERCURIC OXIDE	021908-53-2	18 mg/kg	unknown	unknown
MERCURIC SULFOCYANATE	000592-85-8	46 mg/kg	unknown	unknown
MERCURY(II) BROMIDE (1:2)	007789-47-1	40 mg/kg	unknown	unknown
MERCURY(II) CHLORIDE	007487-94-7	1 mg/kg	unknown	unknown
MERCURY(II) IODIDE	007774-29-0	18 mg/kg	unknown	unknown
MERCURY(II) NITRATE (1:2)	010045-94-0	26 mg/kg	unknown	unknown
METHADONE HYDROCHLORIDE	001095-90-5	30 mg/kg	unknown	unknown

METHANESULFONYL FLUORIDE	000558-25-8	2 mg/kg	unknown	1 ppm
METHOMYL	016752-77-5	17 mg/kg	unknown	77 ppm
METHOXYETHYL MERCURIC ACETATE	000151-38-2	25 mg/kg	unknown	unknown
METHYL 2-CYANOACRYLATE	000137-05-3	unknown	unknown	101 ppm
METHYL CHLOROCARBONATE	000079-22-1	unknown	unknown	88 ppm
METHYL DEMETON METHYL	002587-90-8	20 mg/kg	unknown	unknown
METHYL ETHYL KETONE PEROXIDE	001338-23-4	unknown	unknown	200 ppm
METHYL FLUOROACETATE	000453-18-9	unknown	20 mg/kg	unknown
METHYL FLUOROSULFATE	000421-20-5	unknown	unknown	5 ppm
METHYL HYDRAZINE	000060-34-4	32 mg/kg	95 mg/kg	34 ppm
METHYL ISOCYANATE	000624-83-9	51 mg/kg	213 mg/kg	6.1 ppm
Methyl Mercury	000593-74-8	unknown	unknown	unknown
Methyl Mercury	022967-92-6	58 mg/kg	unkown	unknown
METHYL NITRITE	000624-91-9	unknown	unknown	176 ppm
METHYL PARATHION	000298-00-0	6 mg/kg	unknown	unknown
METHYL PHOSPHONIC DICHLORIDE	000676-97-1	unknown	unknown	26 ppm
METHYL THIOUREA	000598-52-7	50 mg/kg	unknown	unknown
METHYL TRITHION	000953-17-3	48 mg/kg	unknown	unknown
METHYL VINYL SULFONE	003680-02-2	unknown	32 mg/kg	unknown
METHYLACETOXYMALONONITRILE	007790-01-4	unknown	110 mg/kg	unknown
METHYLCARBAMIC ACID-4-METHYLTHIO-m-TOLYL ESTER	003566-00-5	50 mg/kg	unknown	unknown
METHYLCARBAMOYLETHYL ACRYLATE	059163-97-2	unknown	200 mg/kg	unknown
METHYLCARBAMOYLMETHYLAMINOMETHYLPHOSPHONIC ACID	098565-18-5	>5 mg/kg	unknown	unknown
METHYLENE BIS(4-CYCLOHEXYLLSOCYANATE)	005124-30-1	9900 mg/kg	unknown	unknown
METHYL-N-(b-CHLOROETHYL)-N-NITROSOCARBAMATE	013589-15-6	20 mg/kg	unknown	unknown
	007417-			

METHYLNITROSOACETAMIDE	67-6	20 mg/kg	unknown	unknown
METHYL-PHENYLETHYL-NITROSAMINE	013256-11-6	48 mg/kg	unknown	unknown
METHYLPHENYLPHOSPHORAMIDIC ACID DIETHYL ESTER	052670-78-7	41 mg/k	unknown	unknown
METHYLPHOSPHODITHIOIC ACID-S-(((p-CHLOROPHENYL)THIO)METHYL)-O-METHYL ESTER	018466-11-0	31 mg/kg	unknown	unknown
METHYLPHOSPHONODITHIOIC ACID O-METHYL ESTER, S-ESTER with 2-MERCAPTO-N-METHYLACETAMIDE	018278-44-9	10 mg/kg	unknown	unknown
METHYLPHOSPHONOTHIOIC ACID-O-(4-NITROPHENYL)-O-PHENYL ESTER	002665-30-7	8 mg/kg	unknown	unknown
MEVINPHOS	007786-34-7	3 mg/kg	unknown	unknown
MITOCROMIN	011043-98-4	13 mg/kg	unknown	unknown
MITOXANTRONE HYDROCHLORIDE	070476-82-3	unknown	125 mg/kg	unknown
MONENSIN SODIUM	022373-78-0	29 mg/kg	unknown	unknown
MONILIFORMIN	031876-38-7	41 mg/kg	unknown	unknown
MONOCROTOPHOS	006923-22-4	8 mg/kg	unknown	unknown
m-sec-BUTYLPHENYL-N-METHYLCARBAMATE	000673-19-8	10 mg/kg	unknown	unknown
N-(2-CHLORO ETHYL)DIETHYLAMINE	000100-35-6	17 mg/kg	unknown	unknown
N-(2-CHLOROETHYL)-2-ETHOXY-5-NITROBENZYLAMINE	056538-02-4	25 mg/kg	unknown	unknown
N-(2-CHLOROETHYL)AMINOMETHYL-4-HYDROXYNITROBENZENE	056538-00-2	25 mg/kg	unknown	unknown
N-(2-CHLOROETHYL)AMINOMETHYL-4-METHOXYNITROBENZENE	056538-01-3	28 mg/kg	unknown	unknown
N-(2-ETHYLHEXYL)CYCLOHEXYLAMINE	005432-61-1	unknown	110 mg/kg	unknown
N-(3-(1-ETHYL-1-METHYLPROPYL)-5-ISOXAZOLYL)-2,6-DIMETHOXYBENZAMIDE	082558-50-7	unknown	>200 mg/k	unknown
N-(BIS(1-AZIRIDINYL)PHOSPHINYL)BENZAMIDE	004110-66-1	50 mg/kg	unknown	unknown
N,N'-BIS(2-CHLOROETHYL)-N-NITROSOUREA	000154-93-8	20 mg/kg	unknown	unknown
N,N-DIETHYLAMINOACETONITRILE	003010-02-4	unknown	unknown	125 ppm
N,N-DIMETHYL-N'-(((METHYLAMINO)CARBONYL)OXY)PHENYLMETHANIMIDAMIDE	023422-53-9	20 mg/kg	unknown	unknown
N,N-DIMETHYL-n-DODECYL(2-HYDROXY-3-CHLOROPROPYL)AMMONIUM CHLORIDE	041892-01-7	unknown	200 mg/kg	unknown
N,N-DIMETHYL-n-DODECYL(3-HYDROXYPROPENYL) AMMONIUM CHLORIDE	038094-02-9	unknown	89 mg/kg	unknown
	013463-			

NICKEL CARBONYL	39-3	unknown	unknown	35 ppm
NICOTINE	000054-11-5	50 mg/kg	50 mg/kg	unknown
NICOTINE SULFATE	000065-30-5	50 mg/kg	50 mg/kg	unknown
NITRIC ACID (RED FUMING)	007697-37-2	unknown	unknown	67 ppm
NITROGEN CHLORIDE	010025-85-1	unknown	unknown	112 ppm
NITROGEN DIOXIDE	010102-44-0	unknown	unknown	88 ppm
NITROGEN FLUORIDE OXIDE	013847-65-9	unknown	unknown	24 ppm
NITROGEN MONOXIDE, mixed with NITROGEN TETROXIDE	063907-41-5	unknown	unknown	115 ppm
N-METHYL-N-BENZYLNITROSAMINE	000937-40-6	18 mg/kg	unknown	unknown
N-NITROSO-4-PICOLYLETHYLAMINE	013256-23-0	40 mg/kg	unknown	unknown
N-NITROSODIMETHYLAMINE	000062-75-9	37 mg/kg	unknown	78 ppm
N-NITROSOMETHYLVINYLAMINE	004549-40-0	24 mg/kg	unknown	unknown
N-NITROSO-N-METHYLCYCLOHEXYLAMINE	005432-28-0	30 mg/kg	unknown	unknown
N-NITROSOPHENACETIN		21 mg/kg	unknown	unknown
N-sec-BUTYL-4-tert-BUTYL-2,6-DINITROANILINE	033629-47-9	unknown	200 mg/kg	unknown
o-(1,3-DIOXOLAN-2-YL)PHENYL METHYLCARBAMATE	006988-21-2	25 mg/kg	unknown	unknown
o-(2-CHLORO-4-NITROPHENYL)-o-ISOPROPYL ETHYLPHOSPHONOTHIOATE	000328-04-1	32 mg/kg	unknown	unknown
O-(4-BROMO-2-CHLOROPHENYL)-O-ETHYL-S-PROPYL PHOSPHOROTHIOATE	041198-08-7	unknown	192 mg/kg	unknown
O,O,S-TRIETHYL THIOPHOSPHATE	001186-09-0	27 mg/kg	unknown	unknown
O,O-DIETHYL-O-(2-CHLORO-1,2,5-DICHLOROPHENYLVINYL) PHOSPHOROTHIOATE	001757-18-2	unknown	177 mg/kg	unknown
O,O-DIETHYL-O-2-QUINOXALYLTHIOPHOSPHATE	013593-03-8	26 mg/kg	unknown	unknown
O,O-DIETHYLPHOSPHOROCHLORIDOTHIOATE	002524-04-1	unknown	unknown	20 ppm
O,O-DIETHYL-S-(CARBETHOXY)METHYL PHOSPHOROTHIOLATE	002425-25-4	45 mg/kg	unknown	unknown
O,O-DIETHYL-S-(N-ETHOXYCARBONYL-N-METHYLCARBAMOYLMETHYL) PHOSPHORODITHIOATE	002595-54-2	36 mg/kg	unknown	unknown
O,O-DIMETHYL-S-(5-METHOXY-1,3,4-THIADIAZOLINYL-3-METHYL) DITHIOPHOSPHATE	000950-37-8	20 mg/kg	200 mg/kg	unknown
O,S,S-TRIMETHYL PHOSPHORODITHIOATE	022608-53-3	26 mg/kg	unknown	unknown

O,S-DIETHYL METHYLTHIOPHOSPHONATE	002511-10-6	6 mg/kg	unknown	unknown
O,S-DIMETHYL PHOSPHORAMIDOTHIOATE	010265-92-6	unknown	118 mg/kg	unknown
o-ARSENIC ACID	007778-39-4	48 mg/kg	unknown	unknown
OCHRATOXIN	037203-43-3	20 mg/kg	unknown	unknown
OCTACHLOROCAMPHENE	001319-80-8	40 mg/kg	unknown	unknown
OCTACHLORODIBENZODIOXIN	003268-87-9	1 mg/kg	unknown	unknown
OCTAMETHYLPYROPHOSPHORAMIDE	000152-16-9	5 mg/kg	unknown	unknown
O-ETHYL-O-(4-METHYLTHIO-m-TOLYL)	003568-56-7	5 mg/kg	unknown	unknown
O-ETHYL-S,S-DIPROPYLPHOSPHORODITHIOATE	013194-48-4	34 mg/kg	26 mg/kg	unknown
O-ETHYL-S-PROPYL-O-(2,4,6-TRICHLOROPHENYL) PHOSPHOROTHIOATE	038524-82-2	unknown	108 mg/kg	unknown
O-PHENYL-N,N'-DIMETHYL PHOSPHORODIAMIDATE	001754-58-1	unknown	100 mg/kg	unknown
o-sec-BUTYL-4,6-DINITROPHENOLTRIETHANOLAMINE SALT	006420-47-9	37 mg/kg	unknown	unknown
OSMIUM TETROXIDE	020816-12-0	unknown	unknown	unknown
OXAMNIQUINE	021738-42-1	30 mg/kg	unknown	unknown
OXYGEN DIFLUORIDE	007783-41-7	unknown	unknown	136 ppm
PARATHION	000056-38-2	2 mg/kg	unknown	unknown
p-CHLORO-5,10-DIMETHYL-2,4-DIOXA-p-THIONO-3-PHOSPHABICYCLO(4.4.0)DECANE	010140-91-7	unknown	200 mg/kg	unknown
PENTABORANE(9)	019624-22-7	unknown	unknown	6 ppm
PENTACHLOROPHENOL	000087-86-5	27 mg/kg	unknown	unknown
PERCHLOROMETHYL MERCAPTAN	000594-42-3	82.6 mg/kg	1410 mg/kg	260 mg/m3
PERFLUOROISOBUTYLENE	000382-21-8	unknown	unknown	500 ppb
PEROXYACETYL NITRATE	002278-22-0	unknown	unknown	95 ppm
PHENIPRAZINE	000055-52-7	34 mg/kg	unknown	unknown
PHENTANYL	000437-38-7	18 mg/kg	unknown	unknown
PHENTANYL CITRATE	000990-73-8	18 mg/kg	unknown	unknown
	008004-	2460		

Phenyl Etherbiphenyl Mixture (vapor)	13-5	mg/kg	unknown	unknown
PHENYL MERCAPTAN	000108-98-5	46 mg/kg	unknown	33 ppm
Phenylmercuric Acetate	000062-38-4	58 mg/kg	unknown	unknown
Phenylmercuric Oleate	000104-60-9	58 mg/kg	unknown	unknown
PHENYLMERCURY CATECHOLATE	003688-11-7	30 mg/kg	unknown	unknown
PHENYLPHOSPHINE	000638-21-1	unknown	unknown	38 ppm
PHORATE	000298-02-2	1 mg/kg	99 mg/kg	unknown
PHOSFOLAN	000947-02-4	unknown	23 mg/kg	unknown
Phosgene	000075-44-5	unknown	unknown	75 ppm
PHOSPHINE	007803-51-2	unknown	unknown	11 ppm
PHOSPHORIC ACID DIMETHYL-p-(METHYLTHIO) PHENYL ESTER	003254-63-5	7 mg/kg	48 mg/kg	unknown
PHOSPHORIC ACID, BIS(3-CHLOROPROPYL) p-NITROPHENYL ESTER	014663-71-9	33 mg/kg	unknown	unknown
PHOSPHORIC ACID, DIMETHYL-4-NITRO-m-TOLYL ESTER	002255-17-6	24 mg/kg	unknown	unknown
PHOSPHORODITHIOIC ACID, O,O-DIMETHYL-S-(2-ETHYLTHIO)ETHYL ESTER	000640-15-3	40 mg/kg	unknown	unknown
PHOSPHOROTHIOIC ACID, O-(2-CHLORO-1-ISOPROPYLIMIDAZOL-4-YL) O,O-DIETHYL ESTER	042509-80-8	40 mg/kg	unknown	unknown
PHOSPHOROTHIOIC ACID, O-ETHYL S-(p-TOLYL) ESTER	063980-89-2	50 mg/kg	unknown	unknown
PHOSPHOROTHIOIC ACID, O-ISOPROPYL O-METHYL O-(p-NITROPHENYL) ESTER	013955-12-9	5 mg/kg	unknown	unknown
PHOSPHOROTHIOIC ACID, S-((1,3-DIHYDRO-1,3-DIOXO-2H-ISOINDOL-2-YL)METHYL) O,O-DIMETHYL	003735-33-9	50 mg/kg	unknown	unknown
Phosphorous Trichloride	002125-68-3	18 mg/kg	1260 mg/kg	104 ppm
PHOSPHORUS OXYCHLORIDE	010025-87-3	unknown	unknown	32 ppm
PHOSPHORUS TRICHLORIDE	007719-12-2	18 mg/kg	unknown	104 ppm
PIPERONYL BUTOXIDE	000051-03-6	unknown	200 mg/kg	unknown
PLASTICIZER 4GO	018268-70-7	18 mg/kg	unknown	unknown
p-NITROBENZONITRILE	000619-72-7	30 mg/kg	unknown	unknown
POLYETHER DIAMINE L-1000		unknown	50 mg/kg	unknown
POTASAN	000299-45-6	19 mg/kg	unknown	unknown

POTASSIUM ARSENITE	013464-35-2	14 mg/kg	unknown	unknown
POTASSIUM AZIDE	020762-60-1	27 mg/kg	unknown	unknown
POTASSIUM CYANIDE	000151-50-8	5 mg/kg	unknown	unknown
PROPARGYL ALCOHOL	000107-19-7	20 mg/kg	unknown	unknown
PROPIONONITRILE	000107-12-0	39 mg/kg	unknown	unknown
PROPYLENE IMINE	000075-55-8	19 mg/kg	unknown	unknown
PROTOVERATRINE A	000143-57-7	5 mg/kg	unknown	unknown
p-tert-BUTYLTOLUENE	000098-51-1	unknown	unknown	165 ppm
RETRORSINE-N-OXIDE	015503-86-3	48 mg/kg	unknown	unknown
S-(ETHYLSULFINYL)METHYL O,O-DIISOPROPYL PHOSPHORODITHIOATE	005827-05-4	25 mg/kg	unknown	unknown
S,S,S-TRIMETHYL PHOSPHOROTRITHIOATE	000681-71-0	30 mg/kg	unknown	unknown
S,S-DIPROPYL METHYLPHOSPHONOTRITHIOATE	000996-05-4	18 mg/kg	unknown	unknown
SELENIUM HEXAFLUORIDE	007783-79-1	unknown	unknown	unknown
SELENIUM MONOSULFIDE	007446-34-6	38 mg/kg	unknown	unknown
SELENOUREA	000630-10-4	50 mg/kg	unknown	unknown
SODIUM ARSENITE	007784-46-5	41 mg/kg	unknown	unknown
SODIUM ARSENITE	013464-37-4	10 mg/kg	unknown	unknown
SODIUM AZIDE	026628-22-8	27 mg/kg	20 mg/kg	unknown
SODIUM DICHROMATE	010588-01-9	50 mg/kg	unknown	unknown
SODIUM HEXACYCLONATE	007009-49-6	20 mg/kg	unknown	unknown
SODIUM SELENITE	010102-18-8	7 mg/kg	unknown	unknown
STIBINE	007803-52-3	unknown	unknown	unknown
STREPTOVITACIN A	000523-86-4	3 mg/kg	unknown	unknown
STRYCHNINE	000057-24-9	2.3 mg/kg	unknown	unknown
SULFOTEP	003689-24-5	5 mg/kg	20 mg/kg	unknown
	010025-			

Sulfur Monochloride	67-9	unknown	unknown	unknown
SULFUR TETRAFLUORIDE	007783-60-0	unknown	unknown	unknown
SWAT	000122-10-1	31 mg/kg	unknown	unknown
TAUROMYCETIN	102418-13-3	50 mg/kg	unknown	unknown
TCDD	001746-01-6	20 mg/kg	unknown	unknown
Tellurium Hexafluoride	007783-80-4	unknown	unknown	unknown
TETRACHLOROISOPHTHALONITRILE	001897-45-6	10 mg/kg	unknown	unknown
TETRAETHYLPYROPHOSPHATE	000107-49-3	500 ug/kg	unknown	unknown
TETRAETHYLSTANNANE	000597-64-8	16 mg/kg	unknown	unknown
TETRA-N-BUTYLPHOSPHONIUM CHLORIDE	002304-30-5	unknown	121 mg/kg	unknown
Tetranitromethane	000509-14-8	130 mg/kg	unknown	18 ppm
THALLIUM	007440-28-0	unknown	unknown	unknown
THALLIUM SULFATE	010031-59-1	16 mg/kg	unknown	unknown
THALLIUM(I) SULFATE (2:1)	007446-18-6	16 mg/kg	unknown	unknown
THALLIUM(III) OXIDE	001314-32-5	44 mg/kg	unknown	unknown
Thimerosal	000054-64-8	58 mg/kg	unkown	unknown
THIMET SULFOXIDE	002588-03-6	2 mg/kg	unknown	unknown
THIOPHOSPHORYL CHLORIDE	003982-91-0	unknown	unknown	20 ppm
TOLUENE-2,4-DIISOCYANATE	000584-84-9	5800 mg/kg	unknown	14 ppm
TRIBUTYLLEAD ACETATE	002587-82-8	2 mg/kg	unknown	unknown
TRICHLOROACRYLOYL CHLORIDE	000815-58-7	unknown	unknown	107 ppm
TRIISOPROPYLTIN ACETATE	019464-55-2	44 mg/kg	unknown	unknown
TRIMETHOXY SILANE	002487-90-3	unknown	unknown	125 ppm
TRIMETHYLTIN ACETATE	001118-14-5	9 mg/kg	unknown	unknown
TRI-n-PROPYL LEAD CHLORIDE	001520-71-4	27 mg/kg	unknown	unknown
TRIS-(1-AZIRIDINYL)PHOSPHINE OXIDE	000545-55-1	37 mg/kg	unknown	unknown

TRIS(2-CHLOROETHYL)AMINE	000555-77-1	5 mg/kg	5 mg/kg	unknown
TRIS(2-HYDROXYETHYL) PHENYLMERCURIAMMONIUM LACTATE	023319-66-6	30 mg/kg	unknown	unknown
TRIS(DIMETHYLAMINO)SILANE	015112-89-7	unknown	unknown	38 ppm
TRISAZIRIDINYLTRIAZINE	000051-18-3	1 mg/kg	unknown	unknown
TUBERCIDIN	000069-33-0	16 mg/kg	unknown	unknown
TUBOCURARINE HYDROCHLORIDE	000057-94-3	28 mg/kg	unknown	unknown
VALINOMYCIN	002001-95-8	4 mg/kg	5 mg/kg	unknown
VANADIUM PENTOXIDE (dust)	001314-62-1	10 mg/kg	unknown	unknown
VERATENSINE	063951-45-1	30 mg/kg	unknown	unknown
VERILOID	065072-04-0	12 mg/kg	unknown	unknown
VINYL 2-(BUTYLMERCAPTOETHYL) ETHER	006607-49-4	unknown	10 mg/kg	unknown
ZINC PHOSPHIDE	001314-84-7	12 mg/kg	unknown	unknown
ZINC PYRIDINE-2-THIOL-1-OXIDE	013463-41-7	unknown	100 mg/kg	unknown
ZOMEPIRAC SODIUM	064092-48-4	27 mg/kg	unknown	unknown

MSDS Number: **P6928** * * * * * *Effective Date: 07/09/08* * * * * *Supercedes: 05/19/08*

PROPYLENE GLYCOL

1. Product Identification

Synonyms: 1,2-propanediol; 1,2-dihdroxypropane; methyl glycol; methylethylene glycol
CAS No.: 57-55-6
Molecular Weight: 76.09
Chemical Formula: CH3CHOHCH2OH
Product Codes:
J.T. Baker: 9402, 9403, U510
Mallinckrodt: 1925, 6263

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Propylene Glycol	57-55-6	99 - 100%	Yes

3. Hazards Identification

Emergency Overview

CAUTION! MAY CAUSE IRRITATION TO SKIN AND EYES.

SAF-T-DATA(tm) Ratings (Provided here for your convenience)

Health Rating: 2 - Moderate (Life)
Flammability Rating: 1 - Slight
Reactivity Rating: 1 - Slight
Contact Rating: 1 - Slight
Lab Protective Equip: GOGGLES; LAB COAT; VENT HOOD; PROPER GLOVES
Storage Color Code: Green (General Storage)

Potential Health Effects

Inhalation:
No adverse health effects via inhalation.
Ingestion:
Relatively non-toxic. Ingestion of sizable amount (over 100ml) may cause some gastrointestinal upset and temporary central nervous system depression. Effects appear more severe in individuals with kidney problems.
Skin Contact:
Mild irritant and defatting agent, especially on prolonged contact.
Eye Contact:
May cause transitory stinging and tearing.
Chronic Exposure:
Lactic acidosis, stupor and seizures have been reported following chronic ingestion.
Aggravation of Pre-existing Conditions:
Kidney disorders.

4. First Aid Measures

Inhalation:
Remove to fresh air. Not expected to require first aid measures.
Ingestion:
Not expected to require first aid measures. Give several glasses of water to drink to dilute. If large amounts were swallowed, get medical advice.
Skin Contact:
Remove any contaminated clothing. Wash skin with soap and water for at least 15 minutes. Get medical attention if irritation develops or persists.
Eye Contact:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Call a physician if irritation persists.

Note to Physician:
In case of ingestion, monitor for acidosis and central nervous system changes. Exposed persons with previous kidney dysfunction may require special treatment.

5. Fire Fighting Measures

Fire:
Flash point: 99C (210F) CC
Autoignition temperature: 371C (700F)
Flammable limits in air % by volume:
lel: 2.6; uel: 12.5
Material can support combustion.
Explosion:
Containers may explode in heat or fire.
Fire Extinguishing Media:
Dry chemical, foam, water or carbon dioxide.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. Move exposed containers from fire area, if it can be done without risk. Use water to keep fire-exposed containers cool.

6. Accidental Release Measures

Ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering. Contain and recover liquid when possible. Use non-sparking tools and equipment. Collect liquid in an appropriate container or absorb with an inert material (e. g., vermiculite, dry sand, earth), and place in a chemical waste container. Do not use combustible materials, such as saw dust. Do not flush to sewer!

7. Handling and Storage

Protect container from physical damage. Store in a cool, dry, ventilated area away from sources of heat, moisture, and incompatible substances. Containers of this material may be hazardous when empty since they retain product residues (vapors, liquid); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
AIHA Workplace Environmental Exposure Level (WEEL): TWA = 10mg/m3.
Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved):
If the exposure limit is exceeded, a half-face respirator with an organic vapor cartridge and particulate filter (NIOSH type P95 or R95 filter) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. A full-face piece respirator with an organic vapor cartridge and particulate filter (NIOSH P100 or R100 filter) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest. Please note that N series filters are not recommended for this material. For emergencies or instances where the exposure levels are not known, use a full-face piece positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:
Clear oily liquid.
Odor:
Odorless.
Solubility:
Miscible in water.
Specific Gravity:
1.0361 @ 20C/4C

pH:
No information found.
% Volatiles by volume @ 21C (70F):
No information found.
Boiling Point:
188.2C (370F)
Melting Point:
-59C (-74F)
Vapor Density (Air=1):
2.6
Vapor Pressure (mm Hg):
0.129 @ 25C (77F)
Evaporation Rate (BuAc=1):
0.01

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
Carbon dioxide and carbon monoxide may form when heated to decomposition. Aldehydes or lactic, pyruvic or acetic acids may also be formed.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Strong oxidizing agents.
Conditions to Avoid:
Heat, flames, ignition sources and incompatibles.

11. Toxicological Information

Oral rat LD50: 20g/kg. Skin rabbit LD50: 20.8g/kg.
Irritation: Eye rabbit/Draize, 500 mg/24H mild.
Investigated as a mutagen and reproductive effector.

--------\Cancer Lists\----------

Ingredient	---NTP Carcinogen--- Known	Anticipated	IARC Category
Propylene Glycol (57-55-6)	No	No	None

12. Ecological Information

Environmental Fate:
When released into the soil, this material is expected to readily biodegrade. When released into the soil, this material is expected to leach into groundwater. When released into water, this material is expected to readily biodegrade. When released into the air, this material is expected to be readily degraded by reaction with photochemically produced hydroxyl radicals. When released into the air, this material is expected to have a half-life between 1 and 10 days.
Environmental Toxicity:
No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

--------\Chemical Inventory Status - Part 1\----------

Ingredient	TSCA	EC	Japan	Australia
Propylene Glycol (57-55-6)	Yes	Yes	Yes	Yes

--------\Chemical Inventory Status - Part 2\----------

Ingredient	Korea	--Canada-- DSL	NDSL	Phil.
Propylene Glycol (57-55-6)	Yes	Yes	No	Yes

--------\Federal, State & International Regulations - Part 1\----------

Ingredient	-SARA 302- RQ	TPQ	------SARA 313------ List	Chemical Catg.
Propylene Glycol (57-55-6)	No	No	No	No

--------\Federal, State & International Regulations - Part 2\----------

Ingredient	CERCLA	-RCRA- 261.33	-TSCA- 8(d)
Propylene Glycol (57-55-6)	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
Reactivity: No (Pure / Liquid)

Australian Hazchem Code: None allocated.
Poison Schedule: None allocated.
WHMIS:
This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: 0 Flammability: 1 Reactivity: 0
Label Hazard Warning:
CAUTION! MAY CAUSE IRRITATION TO SKIN AND EYES.
Label Precautions:
Avoid contact with eyes, skin and clothing.
Wash thoroughly after handling.
Label First Aid:
In case of contact, immediately flush skin or eyes with plenty of water for at least 15 minutes. Call a physician if irritation develops or persists.
Product Use:
Laboratory Reagent.
Revision Information:
MSDS Section(s) changed since last revision of document include: 8.
Disclaimer:
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